S. HRG. 98-1115

OVERSIGHT ON ISSUES RELATING TO THE VA'S DEPARTMENT OF MEDICINE AND SURGERY

HEARING

BEFORE THE

COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES SENATE

NINETY-EIGHTH CONGRESS

SECOND SESSION

ON

CERTAIN ISSUES PERTAINING TO QUALITY ASSURANCE WITHIN THE VA'S DEPARTMENT OF MEDICINE AND SURGERY, INCLUDING THE ROLE OF THE MEDICAL INSPECTOR AND EVALUATION OFFICE

JUNE 6, 1984

Printed for the use of the Committee on Veterans' Affairs

U.S. GOVERNMENT PRINTING OFFICE

39-069 O WASHINGTON : 1984

S761-2

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OVERSIGHT ON ISSUES RELATING TO THE VA's DEPARTMENT OF MEDICINE AND SURGERY

WEDNESDAY, JUNE 6, 1984

U.S. SENATE,
COMMITTEE ON VETERANS' AFFAIRS,
Washington, DC.

The committee met, pursuant to notice, at 10 a.m., in room SR-418, Russell Office Building, Hon. Alan K. Simpson (chairman) presiding.

Present: Chairman Alan K. Simpson (presiding), and Senator Alan Cranston.

Senator CRANSTON [presiding]. The hearing will come to order. Senator Simpson, the chairman, will be here shortly, but I will lead off. I have a brief opening statement I will start with.

I welcome each of you to today's oversight hearing on issues relating to quality assurance within the VA's Department of Medicine and Surgery.

I thank those of you who are appearing as witnesses today for your willingness to share your views and opinions with the committee.

I congratulate the chairman for scheduling this hearing, and for his related request to the Comptroller General for a GAO review of the VA's quality assurance program, particularly of the functioning of the Medical Inspector's office.

I had some fairly strong misgivings in 1980 about the establishment of the Office of Medical Inspector within DM&S and most especially about the continuing role, once that office was established, of the VA's Inspector General regarding issues relating to quality of care and competency of medical professionals at VA health-care facilities.

I think it is an excellent idea for the committee to be looking into these issues again.

I ask unanimous consent that a copy of my August 7, 1980, letter to then Administrator Cleland regarding my concerns about the establishment of the Office of the Medical Inspector appear at this point in the hearing record.

[The letter referred to above follows:]

[illegible]

United States Senate

COMMITTEE ON VETERANS' AFFAIRS

WASHINGTON, D.C. 20510

August 7, 1980

Honorable Max Cleland
Administrator of Veterans' Affairs
810 Vermont Avenue, N.W.
Washington, D.C. 20420

Dear Max,

I am writing with regard to testimony the Committee received at the June 11, 1980, oversight hearing on the activities of the VA Inspector General. At that hearing, the Committee received testimony regarding a proposal currently being discussed between the Inspector General and the Chief Medical Director to establish, within the Department of Medicine and Surgery (DM&S), a Medical Inspector Office to review matters relating to the quality of care and competency of medical professionals at VA health-care facilities.

I am very concerned, Max, that any agreement to establish such an office could have the effect of delegating functions currently performed by the IG's Office to another office within the VA and that such a delegation would compromise the IG's independence. I am also concerned that reviews and investigations undertaken by a Medical Inspector responsible to the Chief Medical Director would lack objectivity and credibility in the eyes of the public.

I would strongly urge that, before approving any agreement to establish a Medical Inspector Office, you assure that such agreement is very carefully drawn so as to delineate clearly the responsibilities of the IG's Office and the DM&S Medical Inspector Office, respectively; that it provide for consultation and coordination between the two offices; that it contain adequate provisions to assure that reviews and investigations carried out by the Medical Inspector Office, particularly where there is controversy surrounding a review or investigation, are conducted in such a manner as to assure public confidence in them; and that the IG retains residual authority and discretion to conduct such investigations at VA medical facilities as he determines to be necessary and appropriate and full responsibility vis-a-vis investigations of the operations of the Medical Inspector Office itself. In this regard, I would note that Mr. Reynolds articulated these same issues in his follow-up, written responses to questions raised at the June 11 hearing.

I look forward to receiving your comments on this issue and, as always, appreciate your continuing cooperation with the Committee.

With warm regards,

Cordially,

Alan Cranston
Chairman

cc: Dr. Donald L. Custis
Honorable Allan L. Reynolds
Guy H. McMichael III, Esq.

Senator CRANSTON. I think it is fair to characterize the establishment of the Medical Inspector's Office as an uneasy attempt to walk a tightrope between, on the one hand, leaving the responsibility for investigating DM&S quality of care issues in a lay entity—the Inspector General's office—that might not have been fully capable of investigating and evaluating such issues and, on the other hand, shifting that responsibility to a professional health-care entity—the Medical Inspector's office—that would not have the resources, the statutory mandate, the independence, or the authority available to the Inspector General, and thus might not have the credibility or the stature needed to carry out the needed investigations or the clout to pursue remedial action where indicated.

It is not clear to me at this point whether this experiment has worked. I'm particularly concerned about the level of resources that are available to the Medical Inspector, the background and training of those who carry out the investigations, as compared to those in other investigative agencies or offices, and, finally, the independence of that office as a staff operation under the Chief Medical Director.

One of the great assets available to the Inspector General is a clear statutory mandate, considerable resources, and the right to investigate matters without restriction. Clearly, the Office of Medical Inspector does not have those attributes and one question we must seek answers to is whether this makes a difference.

I look to today's hearing and related followup activity and the results of GAO review to help shed more light on these questions and to aid the Committee in determining appropriate next steps.

I want to be clear that, in raising these questions and concerns, I am not questioning the commitment of DM&S to provide quality care to all eligible veterans. I do not doubt that commitment. I am also not questioning the personal commitment of any of the DM&S officials involved in current quality assurance efforts.

What is less clear, however, is the true extent of commitment within DM&S to effective quality assurance efforts. The key question in this regard is how best to ensure that the agreed-upon quality of care is realized and, in that regard, how to make evaluations of quality of care and to correct problems that are discovered through such evaluations.

As I indicated a moment ago, one of the most important elements in any quality assurance effort—whether it is with reference to the manufacture of widgets or to providing health care—is the devotion of resources to the effort. How many people are involved? For what portion of their time? The extent of resources allocated is, I believe, a good measure of the degree of commitment to quality assurance.

A closely related element in any quality assurance effort is the backing such an effort receives from top management. How are good efforts by health-care providers rewarded, and unsatisfactory efforts punished?

We must look at all these questions in the context of current DM&S efforts.

Along with these more general questions, I have a number of specific concerns that I intend to pursue as part of the committee's oversight on these quality assurance issues. One such concern—the

supervision of residents in VA facilities—is already the subject of a GAO investigation that I have requested. It is due by the end of this year. This is a crucial quality assurance issue.

Another longstanding concern of mine is how the agency responds to documented instances of malpractice. Over the years, I've attempted to follow up on reported instances of malpractice to determine what disciplinary action was taken in cases in which, as a result of settlements or court decisions, clear examples of misfeasance or malfeasance have been identified.

From what I've seen, in far too many cases, the Department has been unwilling or unable to take strong disciplinary action. I believe that this pattern sends an unmistakable signal to others in DM&S that professional malpractice may be no big deal. That is plainly the wrong signal, and efforts must be made to correct any such impression.

I believe this would be a fruitful area of inquiry for the Inspector General and perhaps the GAO

On the other side of the coin, I am concerned that quality assurance efforts not be used as a guise for punishing health-care personnel, particularly those who may have blown the whistle on questionable practices at their facilities.

Due process guarantees must be maintained and, as appropriate, strengthened so as to protect the rights of individual health-care personnel so that what they have to say about the system can be heard.

Without a willingness on the part of individuals in the Department of Medicine and Surgery to come forward and be heard, no quality assurance program can be fully effective.

As I noted earlier, I have had and continue to have reservations about the effectiveness of the quality assurance methods used in DM&S, and particularly about the role assigned to the Office of the Medical Inspector. I intend to pursue these and other quality assurance concerns in the context of this hearing.

Again, I thank all of you who are testifying today for your willingness to assist the committee.

Although I have to leave early, I will be reviewing the testimony carefully and submitting written questions.

I now welcome the first witness, John A. Gronvall, M.D., Acting Chief Medical Director of the Veterans' Administration. Dr. Gronvall is accompanied by Kenneth E. Lindsay, M.D., Medical Inspector; Robert W. Love, Jr., M.D., Associate Director for the Medical Inspector and Evaluation Office; and Frank S. Sato, Inspector General of the Veterans' Administration.

TESTIMONY OF JOHN A. GRONVALL, M.D., ACTING CHIEF MEDICAL DIRECTOR, VETERANS' ADMINISTRATION, ACCOMPANIED BY KENNETH E. LINDSAY, M.D., MEDICAL INSPECTOR; ROBERT W. LOVE, JR., M.D., ASSOCIATE DIRECTOR FOR THE MEDICAL INSPECTOR AND EVALUATION OFFICE; AND FRANK S. SATO, INSPECTOR GENERAL OF THE VETERANS' ADMINISTRATION

Dr. GRONVALL. Thank you very much, Mr. Chairman.

I want to start by saying that for me personally, it's a very great pleasure to appear before you and the committee today.

I can't resist saying that I hope the fact that this is a D-day anniversary is not indicative of the portent of this committee hearing.

We, in fact, look forward very much to this meeting with you.

I have a written statement which I would like to submit for the record.

Senator CRANSTON. Fine. It will be received.

Dr. GRONVALL. Thank you.

You've already introduced the three colleagues who are here at the table with me, Dr. Kenneth Lindsay, who heads our Medical Inspector Office; Dr. Robert Love, the Associate Director of the Office; and Mr. Frank Sato, who is the Inspector General for the Veterans' Administration.

The provision of high quality care to our veteran patients is, of course, the overriding and primary goal of the Department of Medicine and Surgery.

It's true that practically every decision we make in the Department and practically every action we take does have quality of care implications. But, it is clear that in order to express a more systematic and constant concern for quality of care, we have to have a systematic evaluation system and it is that system that we're here to describe today.

The primary responsibility for that system within the Department rests in the Medical Inspector and Evaluation Office. This office ensures that there is systematic evaluation and feedback of the results of such evaluations so that corrective action can be taken.

The Medical Inspector is primarily concerned with acting on reported incidents of poor quality care, or other situations in our medical centers that could lower or interfere with the quality of care being delivered.

The primary function of the Evaluation Division within that office is to establish and maintain a program that systematically evaluates quality of care at each of our medical centers.

The Medical Inspector Office itself was established in September 1980, following hearings before this committee.

This office consists of three individuals, a physician supported by two administrative and support personnel. It is organizationally a part of the Chief Medical Director and Deputy Chief Medical Director Office as a staff element.

We have kept the office deliberately small, but it has available to it resources in terms of people from throughout our entire hospital system. The Medical Inspector reviews required patient incident reports that are submitted whenever there is an adverse incident involving a patient and the Medical Inspector follows up and investigates allegations and complaints about quality of care that might come from any source.

The detailed mechanism by which this is carried out is presented in my formal testimony.

The Medical Inspector, I believe, has good working relationships with all of the VA organizational elements, including the Inspector General for the Veterans' Administration.

The Medical Inspector's Office does not have line authority. It functions as a staff office, but our line officials, importantly, the Associate Deputy Chief Medical Director and the Regional Direc-

tors, do carry out the actions necessary to implement change or take action based on the findings from these investigations.

The Inspector General of the Veterans' Administration exercises oversight of our activities through an established liaison with the Medical Inspector.

This takes place through regularly scheduled meetings as well as through regular telephone and other kinds of informal contact. All of the cases that are reviewed by the Medical Inspector are reported to the Inspector General and copies of all medical center investigations are routed to the Inspector General.

Let me make some brief comments about the evaluation office, the other component of this office. The evaluation office is responsible for the ongoing program of systematic review of all of the services we provide in our medical centers.

Some of these reviews are conducted within the authority of the medical center itself, others are conducted by departmental personnel who are external to the medical center. Additional reviews are conducted by agency personnel who are external to the Department. Finally we are reviewed by many bodies that are in turn external to the Veterans' Administration.

In fact, there are approximately 40 reviewing bodies that either survey, audit, evaluate or inspect our medical care facilities.

The cornerstone of the evaluation activity resides in the systematic internal review program and the systematic external review program. The medical center director is responsible for an internal review program that provides ongoing monitoring of patient care activities, reviewing such things as surgical care review, credentialing, assignment of clinical privileges and other similar clinical and administrative activities.

Again, those various functions are detailed in my formal statement.

The systematic external review program [SERP] is a peer review mechanism that evaluates the quality of care as well as the effectiveness of the internal review program in each of the VA facilities.

This review is external to the medical center itself, yet it is internal to the Department of Medicine and Surgery in a way that we believe allows it to be effective, yet tailored to meet the needs of the Department.

The systematic external review program function consists of a group of team leaders who organize and lead survey teams that conduct 1-week surveys of our medical centers. Each of these teams is composed of 4 to 10 team members who themselves come from other medical facilities that are similar to the one being surveyed. Each team includes physicians, a dentist, a nurse, and appropriate administrative personnel. These teams evaluate the entire medical center. They review both patient care and support services. They also make it a point to review areas of special concern, such as care of female veterans, agent orange activities, supervision of house staffs, and the programs of medical care for former prisoners of war.

These external reviews are conducted on a variable cycle, but not less than once each 4 years. A period of reassessment is assigned after each review and this can be a 1-, 2-, 3- or 4-year period.

I want to at least mention, by title, the two other elements of our evaluation office. These are the patient satisfaction section that administers a biannual patient questionnaire that assesses patient satisfaction with care, and, finally, a reports management section that coordinates our responses to all external audits, such as GAO reports, Joint Commission on Accreditation of Hospitals reports, et cetera.

Mr. Chairman, I believe we do give a great deal of attention to assuring quality of services at all levels. This is our ultimate goal in our health-care system, and I can assure you of my own very strong commitment to the provision of quality health care.

This concludes my opening comments, and I'll be pleased to respond to questions.

Chairman SIMPSON [presiding]. Thank you very much, Dr. Gronvall. And, I appreciate that, and I want to thank Senator Cranston and the minority staff for going forward here appropriately, and I appreciate your facilitating the hearing, Al. As always, done fairly and efficiently.

I guess Al gets up at dawn and runs, and I run down at dawn, you see, and we have different clocks, and, so, that's part of our interesting relationship.

Without objection, I will place my opening statement at this point in the hearing record.

[The opening statement of Hon. Alan K. Simpson, chairman of the Senate Committee on Veterans' Affairs, follows:]

OPENING STATEMENT OF HON. ALAN K. SIMPSON, CHAIRMAN OF THE SENATE COMMITTEE ON VETERANS' AFFAIRS

GOOD MORNING AND WELCOME TO THE COMMITTEE ON VETERANS' AFFAIRS OVERSIGHT HEARING ON ISSUES PERTAINING TO QUALITY ASSURANCE WITHIN THE VA'S DEPARTMENT OF MEDICINE AND SURGERY. THE PURPOSE OF THE HEARING TODAY IS TO BEGIN A REVIEW OF THE VA'S POLICIES AND ACTIVITIES WITH RESPECT TO QUALITY ASSURANCE, INCLUDING THE ROLE OF THE MEDICAL INSPECTOR AND EVALUATION OFFICE IN ENSURING THAT SUCH POLICIES ARE IMPLEMENTED AND MONITORED.

IN 1980, DURING HEARINGS ON ACTIVITIES OF THE VA'S OFFICE OF INSPECTOR GENERAL, THIS COMMITTEE CONSIDERED THE QUESTION OF WHETHER AN OFFICE OF MEDICAL INSPECTOR SHOULD BE ESTABLISHED IN THE DEPARTMENT OF MEDICINE AND SURGERY. LATER THAT SAME YEAR, SUCH AN OFFICE WAS SET UP BY THE VA AND SUBSEQUENTLY, IN 1981, RESPONSIBILITY FOR THE OVERSIGHT OF ALL QUALITY ASSURANCE MATTERS WAS ORGANIZED UNDER THE UMBRELLA OF THE OFFICE OF MEDICAL INSPECTOR AND EVALUATION AS WE KNOW IT

TODAY.

IT IS THE VIEW OF THIS CHAIRMAN AND THIS COMMITTEE THAT THE MISSION WITH WHICH THE MEDICAL INSPECTOR HAS BEEN CHARGED -- TO OVERSEE THE MONITORING OF THE QUALITY OF CARE IN ALL VA MEDICAL FACILITIES AND THE COMPETENCY OF ALL DEPARTMENT OF MEDICINE AND SURGERY HEALTH CARE PERSONNEL -- MUST BE A HIGH PRIORITY OF THE VA. AND SO, WE ARE HERE TODAY TO LEARN MORE ABOUT HOW THIS MOST IMPORTANT OFFICE OPERATES AND HOW ITS NUMEROUS ACTIVITIES -- INVESTIGATIONS, PEER REVIEWS, PATIENT SATISFACTION SURVEYS, AND MUCH MORE -- SUPPORT ITS MISSION.

IN THIS REGARD, WE WILL EXAMINE SEVERAL IMPORTANT ISSUES. FIRST, ARE THERE ANY MAJOR QUALITY OF CARE PROBLEMS PENDING IN THE VA TODAY? AND IF SO, WHICH ONES REQUIRE THE MOST IMMEDIATE ATTENTION?

SECOND, IN A SYSTEM WITH AS MANY DIFFERENT OFFICES AND INDIVIDUALS IN THE QUALITY ASSURANCE PROCESS -- THE INSPECTOR GENERAL, THE MEDICAL INSPECTOR, EVALUATION TEAMS, PROFESSIONAL SERVICES, REGIONAL OFFICES, MEDICAL CENTER DIRECTORS, CREDENTIALING COMMITTEES, BOARDS OF INVESTIGATION, AND OTHERS -- WHERE

DOES THE ULTIMATE RESPONSIBILITY FOR QUALITY ASSURANCE LIE? AND, WITH ALL THESE PLAYERS, EACH PERFORMING IMPORTANT ROLES IN THE PROCESS, HOW IS THE VA ABLE TO ENSURE THAT EFFORTS ARE COORDINATED AND THAT FOLLOW-UP ACTUALLY OCCURS?

THIRD, WHAT STANDARDS AND PROCEDURES ARE APPLIED TO DETERMINE THE COMPETENCY OF PROFESSIONALS AND ARE THESE STANDARDS OPTIONAL OR MANDATORY?

FOURTH, WHERE DOES THE MISSION OF THE MEDICAL INSPECTOR AND EVALUATION OFFICE RANK COMPARED WITH OTHER VA PRIORITIES AND ARE SUFFICIENT RESOURCES ALLOCATED TO ENABLE THE MEDICAL INSPECTOR TO PERFORM THE TASKS NECESSARY TO ACCOMPLISH HIS MISSION?

AND FIFTH, WITHOUT IN-HOUSE MEDICAL EXPERTISE, IS THE INSPECTOR GENERAL ABLE TO EFFECTIVELY OVERSEE THE ACTIVITIES OF THE MEDICAL INSPECTOR AND EVALUATION OFFICE? DOES THE CURRENT PLACEMENT OF THE MEDICAL INSPECTOR WITHIN THE DEPARTMENT OF MEDICINE AND SURGERY ALLOW FOR SUFFICIENT INDEPENDENCE? WHAT ORGANIZATIONAL CHANGES MIGHT BE CONSIDERED TO IMPROVE THIS PROCESS?

ACCORDING TO THE GENERAL ACCOUNTING OFFICE, IN FISCAL YEAR 1983, 956 MALPRACTICE CLAIMS WERE FILED. IN THAT SAME YEAR, THE MEDICAL INSPECTOR INVESTIGATED 241 MEDICAL INDICENTS, INCLUDING 43 SUICIDES AND SUICIDE ATTEMPTS, 59 CASES OF PATIENT ABUSE, AND 67 "POOR QUALITY" OF CARE INCIDENTS. OF THE REQUESTED $629,000 FOR AN OPTIMAL 70 PEER REVIEW SITE VISITS NECESSARY TO MEET THE VA'S OWN ACCREDITATION SCHEDULE, ONLY $276,000 WAS RECEIVED RESULTING IN ONLY 39 SURVEYS.

AND SO, WE ARE HERE TO EXPRESS OUR INTEREST ABOUT THESE MATTERS, LEARN ABOUT THE VA'S VIEWS, AND BEGIN A DIALOGUE WHICH WILL CONTINUE IN THE WEEKS AND MONTHS TO COME, ON QUALITY ASSURANCE, A DIALOGUE WHICH, I AM CONFIDENT, WILL BE OPEN, THOUGHTFUL, RESPONSIBLE AND PRODUCTIVE.

WE ARE ALSO PLEASED TO HAVE REPRESENTATIVES FROM THE DEPARTMENT OF DEFENSE AND FROM THE PRIVATE SECTOR WITH US TODAY WHO WILL PROVIDE VALUABLE INSIGHT INTO THEIR EXPERIENCES WITH QUALITY ASSURANCE.

I DO REQUEST THAT THE WITNESSES SUMMARIZE THEIR REMARKS. WE SHALL THEN ALLOW FOR PERIODS OF QUESTIONING. OF COURSE, THE ENTIRE WRITTEN STATEMENTS OF THE WITNESSES WILL BE INCLUDED IN THE RECORD AT THE APPROPRIATE POINT.

Chairman SIMPSON. I think you have further commitments, Alan, so you may wish to go ahead and ask any questions.

Senator CRANSTON. I thank you very much, Alan.

I'd like to ask just one question of Mr. Sato. Could you explain your relationship with the Medical Inspector, and particularly how your office goes about carrying out oversight of the Medical Inspector's operation?

Can you give us a general outline of that now, and then supplement it later?

Mr. SATO. Yes, sir, Senator.

My relationship with the Medical Inspector's Office, I think, is very good. We do have a close working relationship.

The way the process works is that when we get complaints, via the IG Hotline, that are in the quality of care area, we refer them to the Medical Inspector. He also gets other cases through the normal process.

We meet at least monthly with him, and more often as specific cases come up. The communication and coordination between our two offices is really quite extensive. When they finish a review, we review all of their reports. If there are any questions involved, we get back together.

If appropriate, there may be some further review, but the process is working well, and I personally know of no particular problem involving the process itself.

Senator CRANSTON. How do you evaluate the effectiveness of the program?

Mr. SATO. I think that gets into two areas, Senator. First of all, if it specifically involves a peer review type of an assessment, it is a doctor's or a medical care professional's judgment of patient care. We're not in a position to evaluate that. That is strictly a peer review process.

In other areas involving administrative type matters, and certainly if it involves something that might raise a question about criminal involvement, we would get directly involved.

Senator CRANSTON. Don't you really need some mechanism for measuring how they are doing? Part of the understanding was that you would have been given the capacity to evaluate the effectiveness of the Medical Inspector's office.

Mr. SATO. I think, Senator, that it is more a review of the process per se. I don't know if we could assess their evaluation of how a doctor might have carried out his or her particular judgment or practice. I believe that would have to be done by another doctor, and the reports that come out as a result of the Medical Inspector's reviews are not of a nature that a third party could assess.

Senator CRANSTON. It seems to me there must be some method of evaluating whether or not the job was done by the Medical Inspector. The Congress has to have some confidence that it is being done right.

How do we derive that confidence?

Mr. SATO. My personal judgment is that you are getting into an area that Dr. Custis, Dr. Gronvall, and I have discussed at great lengths. It is the issue of the normal medical peer review in which medical people assess the work of doctors and other medical personnel.

I'm not sure that that is possible for my office to perform the type of review that is ongoing right now.

Senator CRANSTON. Do you know how the Defense Department handles this relationship? Is there a comparable process?

Mr. SATO. I'm generally aware of their process, yes, sir.

Senator CRANSTON. What is it? Is it worthwhile?

Mr. SATO. I think their process is very comparable to what we have in the Veterans' Administration.

As you know, Senator, I spent 25½ years in the Department of Defense and did work in the office that was the predecessor of the current Inspector General's office, so I generally understand how that process is covered.

The reviews that are made by that office generally involve evaluating standards that have been established by the medical professionals. They do not look at the medical judgment of the doctors in the same way.

I think our processes are quite comparable.

Senator CRANSTON. You don't have any comparable set of clear standards which would apply in an evaluation?

Mr. SATO. I'm sorry, sir. I don't quite understand that question.

Senator CRANSTON. You referred to standards of the Defense Department, that set up similar standards in the VA for making evaluations.

Mr. SATO. I think we do—insofar as our processes are concerned—we have similar standards.

I was alluding to the fact that even in the VA, there are certain established standards, and when we audit or investigate, we measure against those standards. For example, in an earlier review of renal transplant facilities, we noted the number of surgical procedures that would be required in order to maintain proficiency. We audited against those standards, and made some recommendations.

These are the types of evaluations we can make. However, we would not make a judgment as to whether the doctors had appropriately carried out their medical responsibilities.

Senator CRANSTON. Al, thank you very much. I think we have to see how the Department of Defense carries out its functions to see if they have a clearer sense in evaluating the quality assurance processes.

Chairman SIMPSON. Now, do you have a feeling that they do have a clearer understanding?

Senator CRANSTON. I don't know. We have to find that out.

Chairman SIMPSON. From what I'm reading, the non-physician audit seems to be working. We'll find out.

But, I think it's a critically important thing. You and I were both involved deeply when Frank Sato came on the scene and we want to be sure that he is independent and is able to do what he is supposed to do, and I think that's critical.

Well, thank you, Al, and I do have a few questions for Dr. Gronvall.

It has been said that there are certain disincentives to providing a medical peer review including the difficulty of monitoring one's professional and personal associates and the fear of possible retaliation.

In your opinion, what are the greatest difficulties or disincentives to establishing an effective quality assurance program or policy?

Dr. GRONVALL. You refer to disincentives, but I would say at a fairly broad or general level that I believe a fundamental hallmark of the definition of a profession, such as medicine or law, is a commitment that's undertaken by professionals to be responsible for peer review, peer accountability, and ultimately an assessment of the quality of function of their professional colleagues.

In the medical profession, those principles are inculcated in medical students during the time they're in medical school. They are built in to many kinds of peer review systems that operate within the medical profession and within hospitals, and it is clearly the case that there are regular instances where groups of professionals, physicians in this case, based on their judgment about the competence of other physicians who practice, take action to limit the privileges of a physician colleague, remove those privileges entirely or take actions that constrain or prevent another physician from practicing.

So, while those actions are difficult and in a sense, expose the individual taking them, to some of the things that you make reference to, again, I believe that assumption of that as a professional responsibility and the exercise of it is the mark of a profession in the truest sense of the word profession.

Chairman SIMPSON. I think you're right, and what you say is absolutely philosophically so. I came from a professional practice of law, and one of the most difficult things we did in that profession was to try to monitor our fellow professionals. It's very difficult and very unpleasant, wretched, in many ways, and, so, because it is that way, it is seldom done.

And, that is at least the way it is in the private sector with regard to another profession, that I am ever more fully aware of than the medical profession, but it is tough. It puts you in conflict with your peers and I know that it must be troublesome.

It's been said that, I think, clearly that only physicians have the capability of monitoring other physicians, and the VA's current organizational structure for quality assurance uses the Department of Medicine and Surgery physicians to monitor the quality assurance program and activities.

As a policymaker, what are the advantages of that particular procedure?

Dr. GRONVALL. I think there are a number of advantages that I could comment on. As a preamble to that comment, I would say that I view as a primary responsibility of the Chief Medical Director the operation of a quality medical care system for veterans. That carries with it a very clear responsibility to ensure that there is within the Department an operable and operating peer judgment system that, in fact, does take action when necessary to deal with physicians who are not functioning competently.

That responsibility is inherent in the function of the Chief Medical Director.

Having said that, I believe that since the peer review system is a part of the Department, and since the judgments are made by physicians who are part of the Department, the judgments have credi-

bility. They are made by knowledgeable physicians who are familiar with the challenges of providing care to veterans and familiar with the way the Department works. As a result, recommendations are more likely to be stated in a way and described in a way and supported with evidence that allows effective management action to be taken within the Department either to deal with the individual who may be at fault in a given instance, or where necessary, to change the system, change the standards or change whatever is necessary to correct the problem that's identified.

I believe that having that peer review responsibility within the Department provides the organized way in which the Chief Medical Director can meet the statutory responsibility of the Chief Medical Director for operating and continuing to operate a quality medical care system.

I should add that the kind of judgments being made by physicians within the VA are subject to outside scrutiny. We are reviewed by many bodies from outside the VA, who conduct evaluations, assessments, accreditations, using physicians from the private sector, from medicine outside the VA.

So, we do have the benefit of judgments by physicians who are not organizationally part of the Department itself. But, again, the cornerstone, I believe, is the system within the Department itself.

Chairman SIMPSON. Yes, sir. Let me ask you or anyone on the panel who cares to respond, for fiscal year 1983, I understand there were 956 malpractice suits filed with the VA. Is that a correct figure?

Dr. GRONVALL. I haven't reviewed those figures recently, I believe that I'd have to ask others.

Chairman SIMPSON. Sure.

Dr. GRONVALL. We have a representative of the General Counsel's office, who can confirm that.

Mr. KRUMP. Yes, sir. My name is Gary Krump, and I'm with the General Counsel's office at the VA, and that is approximately the correct figure.

Chairman SIMPSON. Then, how many of those were settled, how many were denied, about how many are still pending?

Mr. KRUMP. Sir, I don't have that information with me, and I'd like to provide that for the record.

Chairman SIMPSON. All right. If you would, please.

[Subsequently, the Veterans' Administration submitted the following information:

In fiscal year 1983, there were 221 administrative claims that were settled, 526 that were denied. At the conclusion of the fiscal year there were 895 claims pending.

Chairman SIMPSON. For that same year, what was the mix or the kinds of cases that were filed, and what are the most often claimed categories of cases?

Mr. KRUMP. Well, again, sir, I don't have that information with me, but we will be happy to provide it for the record.

[Subsequently, the Veterans' Administration submitted the following information:

The Veterans' Administration does not maintain these types of statistics.

Chairman SIMPSON. No one else has that information? You don't even have a general idea of that, without going to the records?

Mr. KRUMP. No, sir; in my case, I am here with a different group, in the General Counsel's office, and that specific group doesn't have a representative here today.

Chairman SIMPSON. I would think that would be a very important thing to have available. It's one piece of information that indicates quality of care and aids those involved with that area or those having oversight over that area.

Dr. GRONVALL. Mr. Chairman, I would be pleased to give you some expansion of that information based on the data that I have with me.

Of the 956 claims that were received in 1983, 747 were either settled or the claim was denied.

At the end of fiscal year 1983, it's my understanding that we had about 895 claims pending in one stage or another of review within the VA.

The malpractice claims and issues are handled in a sense on an individualized basis and through the General Counsel's office. I can't really respond to categorization of them in a way that is very helpful at this time.

However, high on the list in terms of frequency are cases where there are either misdiagnosis or improper treatment or alleged improper treatments in regard to surgical procedures, complications of surgical procedures, or delayed complications that relate to surgery.

Drug therapy is an area again that is fairly frequent, particularly in regard to use of antibiotics, anti-inflammatory drugs, antihypertensives, where there are adverse reactions to drug treatment or concerns expressed about whether the right drug was used.

The particularly life threatening kinds of medical conditions, such as cancer, myocardial infarction, cerebral aneurisms, things of that sort, lead to the greatest expressions of concern about the appropriateness of care, either by the patients or by their families, and, so, patient problems or medical care problems in those cataclysmic kinds of medical conditions also are a source of malpractice complaints.

[Subsequently, the Veterans' Administration submitted the following information:]

In addition to malpractice claims, there were 229 suits filed in fiscal year 1983 alleging medical malpractice in VA facilities. Eighty-three such suits were dismissed, 94 were settled, 17 went to judgment in favor of the person suing and 35 resulted in judgment for the Government.

Chairman SIMPSON. Is there any systematic effort used to collect data on malpractice claims that are filed in the individual medical centers and at the central office level, and, if so, is that data analyzed and used to serve as an indicator or possible evidence of quality care problems or trends in the specific services or centers, in the system as a whole? What's the situation there?

Dr. GRONVALL. I think that I can't really answer the question fully. In order to be really responsive to the level of detail about documentation and assessment of malpractice experience at individual centers, I would have to collect additional information, and I'd be pleased to respond to that.

Chairman SIMPSON. If you would, please. I'm particularly interested in whether data on any malpractice claims has been compared with data collected from the Office of Medical Inspector on the kinds and numbers of investigations that are reported on various medical incidents.

I think that that data has to be coordinated, and I'd like to know whether it is. And, if not, you know, why not?

Dr. GRONVALL. We'd be pleased to supply that information.

[Subsequently, the Veterans' Administration submitted the following information:]

1. No data on malpractice claims has been compared with any data collected by the Medical Inspector's office.

2. The reasons for not having done so are due to the fact that no central mechanism for receiving information about malpractice cases exists in the Department of Medicine and Surgery and that until recently the newness of the Medical Inspector's office and its case collection would not have provided data for comparison. We are presently in the process of working out an arrangement with General Counsel for malpractice claim notification and will then enter into a comparison and correlation with the data presently compiled by the Medical Inspector.

Chairman SIMPSON. I don't like to go back over old ground, but at a hearing last June, we discussed an unfortunate incident which we all recall involving a medical resident in a surgical case which occurred in 1981. More than 6 years prior to that, the Inspector General had identified that surgery at that facility wasn't adequately supervised. I'm certain that I will be advised that that will not happen again, but what specific factors account for the VA's failure to act in a timely manner, which resulted in an incident occurring literally years after the problem had been, I think, correctly identified, at least we found that it was correctly identified?

Dr. GRONVALL. Is your inquiry about the specific incident in a specific facility, or a more general level?

Chairman SIMPSON. I think we understand that that is being remedied there, but what I'm saying is, are the conditions still there which would allow that type of thing to occur?

Dr. GRONVALL. Let me make both some specific and some general comments, and Dr. Lindsay may want to amplify then in the instance to which you refer.

Since the incident occurred, we have dismissed the surgeon who was involved and we have also dismissed the Chief of Surgery Service, and, in fact, the Chief of Staff has been replaced at that facility.

I wish that I could tell you that such an adverse incident will never occur again, but I could not in good conscience make that as either a pledge or a prediction.

I think wherever large numbers of medical and surgical procedures are carried out, there will be, unfortunately, under any circumstance, whether that's in the VA or in the private sector, there will be adverse occurrences.

That comment is in no way to excuse the fact that in the incident to which you refer, there had been earlier evidence which had been inadequately acted upon, that was contributory then to the fact that some time later, a very serious incident occurred.

As a result of that incident, in addition to the specific actions I've described at that facility, we have communicated to all of the medical schools with which we're affiliated, we have reviewed in

some detail the issue of supervision of house staff, clarified the responsibility of our medical center director and chief of staff, in relation to the medical school responsibilities.

We have asked for reviews of supervision at our medical centers, and have received comments back from them. All of that has been with the intent of calling attention to the requirements of appropriate supervision, responsibility of the supervising physicians, and of tightening the system of residency supervision throughout all of our hospitals.

So, we have attempted to deal with the problem both at the individual facility and throughout the entire system.

Chairman SIMPSON. I understand that 241 cases of medical incidents were opened by the Medical Inspector for fiscal year 1983, but only 21 site visits were conducted. Because these cases involved, I think, rather serious allegations of unexpected deaths or cases of patient abuse or suicides, suicide attempts or patient assaults, quality of care problems, and other instances, why was it not necessary to conduct a site visit on each of these cases?

Dr. GRONVALL. Let me ask Dr. Lindsay to comment on that question, please.

Chairman SIMPSON. Please.

Dr. LINDSAY. Excuse me. I think the figures you cited are approximately correct.

As we look at the material that comes into us, we make a review and attempt to determine what level of investigation, review, or other action needs to take place.

We find that in many of these instances that are reported to us as well as some of the material we get from other institutions, that we can receive all the information that we require by correspondence with the institutions, asking them for further amplification of the particular problem involved, asking them for amplification as to what they have done to correct it, what they intend to do. In all instances when cases come to us from VA medical centers, investigations have already been conducted by the local institutions.

If further review is necessary it can frequently be handled through written and sometimes telephonic communications.

If the situation is sufficiently severe or if we find it's a recurring problem, then it may be necessary to further investigate the matter, but we don't believe that we need to do so on each individual case because they satisfy us as to the content in many cases.

Chairman SIMPSON. But, are the resources there for that purpose if you chose to do that, are they not?

Dr. LINDSAY. We have not had any problems with resources for that type of activity. Our resources, I might add, Dr. Gronvall alluded to this already, the immediate resources in the office may seem relatively small, but it should be remembered that we have the entire resources of the system.

Any physician, nurse, administrative person in the system is available to go out and make the site visit, if required.

Chairman SIMPSON. Data that we have concerning the Systematic External Review Program [SERP] reveals that 15 VA medical centers have not had a SERP review during the 1980's. Two have not been reviewed since 1978, and one has not been reviewed since 1977.

What factors would account for that fact, that it has been more than 4 years since those facilities have been reviewed and why are they not at the top of the list of facilities to be reviewed under the new accreditation process?

Dr. GRONVALL. Dr. Love heads the evaluation office. Let me ask him to comment on that.

Chairman SIMPSON. Please.

Dr. LOVE. Senator, the resources for the SERP visits have been somewhat limited. We have scheduled approximately 70 visits per year.

Our allocation of travel funds has only allowed us to do, in fiscal year 1982, I believe it was 31, and the other subsequent years have been about 40 to 42.

Why clear back to 1977 has slipped, I'll have to find out. I do not know that. We have tried to review all facilities at least every 4 years.

Chairman SIMPSON. So, you lack the resources to do this?

Dr. LOVE. We have been short on travel funds, yes, sir.

Chairman SIMPSON. And, it has been expressed to the Administrator and others within the system?

Dr. LOVE. It has been expressed to the Deputy Chief Medical Director. I can't answer if it was expressed to the Administrator.

Dr. GRONVALL. Yes, it has.

Chairman SIMPSON. What happened when it happened?

Dr. GRONVALL. I think that the availability of travel funds for all activities in the department that require travel have always been considerably short of the amount judged by each program office and program area as being necessary, and as a generalization, falls short of some idealized standards of how many educational programs we should conduct, how many reviews of this, that or the other SERP should conduct.

It's my judgment in reviewing the overall availability of travel funds in comparison to allocations of various program activities, that the Medical Inspector activities have not been shortchanged. They have been, in my view, dealt with fairly in the allocation of the funds that are available.

Chairman SIMPSON. Well, I'd like to see a comparison of the travel budget for this program and other programs within the VA. I'd like to have that information, and how they deal with their travel and this one and others because if we say that 70 visits should be conducted and there's no resources to do that, it seems like there's a gap there in activity and followthrough and mission.

Dr. GRONVALL. We'd be happy to supply the information.

Chairman SIMPSON. I'd appreciate that.

[Subsequently, the Veterans' Administration submitted the following information:]

FISCAL YEAR 1984 ALLOCATION

[As of June 19, 1984]

Selected DM&S Office	Medical administration employee travel (811.007)	Medical care employee travel (870.007)	Total
Medical inspector/evaluation	$102,842	$198,101	[1] $300,943
Medical information resource [2] management office [MIRMO]	131,000	792,908	923,908
Readjustment counseling	15,369	595,199	610,568
Program analysis and development [MEDIPP]	76,070	86,100	162,170
Administration [3]	192,138	372,776	564,914
Facility engineering, planning [4] and construction [FEPAC]	176,173	37,415	213,588
Professional services [5]	135,446	138,898	274,344
Total	829,038	2,221,397	3,050,435

[1] Includes $247,542 for 41 SERP visits (39 full surveys and 2 followup visits) in fiscal year 1984.
[2] Includes responsibility for implementation of the decentralized hospital computer program [DHCP] and related ADP activities.
[3] Includes responsibility for development of productivity staffing standards and a DRG-based resource allocation methodology, meetings of the strategic management committee, and police training.
[4] Includes responsibility for planning, development, and implementation (in cooperation with the Office of Construction) of the DM&S construction program.
[5] Includes responsibility for the following services: Medical, surgical, pathology, radiology, nuclear medicine, mental health and behavioral sciences, rehabilitation medicine, pharmacy, dietetic, prosthetic and sensory aids, social work, optometry, blind rehabilitation, chaplain, audiology and speech pathology, neurology, spinal cord injury, and podiatric.

Chairman SIMPSON. Just a couple more questions here.

The DOD Office of the Inspector General relies on the medical expertise of an outside physician consultant in certain quality assurance audits.

What is your view of the suggestion to add in-house medical expertise to the staff of the Inspector General to aid him in overseeing the activities of the Medical Inspector?

Dr. GRONVALL. Of course, the Inspector General carries full responsibility on his own for determining his own staff needs and hiring and retaining people in his office. So, I'm not commenting on his authority.

It's my opinion that it would be very difficult for the Inspector General to hire physicians to be full-time continuing members of his staff to engage as a full-time activity in audits or investigations of quality of care.

I think in some opening comments that both you and I made, we pointed to how difficult and awesome, in a sense, unpleasant, that sort of activity is. It is not relished particularly by physicians, and in my experience, physicians who view themselves as being primarily a part of an operating enterprise that is delivering care, are willing, able and ready to engage in such activities on a periodic basis, but when they consider the thought of a full-time career, working, essentially, for a lay auditor outside of an operating medical system, it's my judgment that the quality of physicians who could be attracted to that job and retained in it would not be very high.

Chairman SIMPSON. Well, I'll try to pursue that. I have some other questions. I think I'll just ask them in writing and ask Frank Sato, if I could, just one question.

Would you find it useful to have a physician on board to aid you in your oversight role with respect to the Office of Medical Inspec-

tor, or would you find it more or less useful to be able to rely on the assistance of an outside medical consultant to aid you in those responsibilities?

Mr. SATO. Mr. Chairman, I think there certainly might be situations where having a physician on the staff would be helpful. However, I'd like to stress the point that, insofar as I'm aware, there have been no problems in this particular area, oversight, of the Medical Inspector's Office.

As you know, under the law, we do have the authority to hire experts and consultants, and we would do so if it were necessary. Further, I have had discussions with the Inspector General at HHS. The areas that we look at are similar, and we coordinate back and forth.

I also have discussions with the Inspector General in DOD on similar type areas. To date, we have not had the need to hire a physician from the outside. However, we would do so if necessary.

I might also add that if we needed that type of expertise, I'm sure that where it's appropriate, we could seek help from the Department of Medicine and Surgery and be assured the appropriate independence, as the case would dictate, would be maintained.

One of my other areas of concern is that if we were to hire a physician, that individual might be a generalist, and we would need a specialist, so that may not particularly help us either, and I think that's part of the issue that Dr. Gronvall has alluded to.

So, there are various ramifications, but I think the current system permits us to seek expertise whenever it is appropriate.

Chairman SIMPSON. So, you have the authority, but you've never used that authority?

Mr. SATO. I have not seen the need to exercise that authority.

Chairman SIMPSON. When you do see the need, you wouldn't hesitate to use that authority?

Mr. SATO. No sir, I would not hesitate to use that authority.

Chairman SIMPSON. For specialists or generalists or others?

Mr. SATO. Yes, sir; that is correct.

Chairman SIMPSON. OK.

Dr. GRONVALL. Mr. Chairman?

Chairman SIMPSON. Yes?

Dr. GRONVALL. May I just clarify that the comment that I gave about the quality of a physician who would be a member of Mr. Sato's staff was focused only on the idea of him hiring a person full-time on a permanent basis would engage in audits.

That comment would not apply to engaging medical consultative assistance.

Chairman SIMPSON. Very well. I thank you very much for your assistance, and I wish you well, Doctor, in performing this very important duty of Acting Chief Medical Director.

Thank you very much. I appreciate your being here.

Dr. GRONVALL. Thank you, Mr. Chairman.

[The prepared statement of John A. Gronvall, M.D., Acting Chief Medical Director, Department of Medicine and Surgery, Veterans' Administration, and the responses of the Veterans' Administration and Frank S. Sato, Inspector General of the Veterans' Administra-

tion, to written questions submitted by Hon. Alan K. Simpson, Chairman of the Senate Committee on Veterans' Affairs, and Hon. Alan Cranston, Ranking Minority Member of the Senate Committee on Veterans' Affairs, follow:]

PREPARED STATEMENT OF JOHN A. GRONVALL, M.D., ACTING CHIEF MEDICAL DIRECTOR, DEPARTMENT OF MEDICINE AND SURGERY, VETERANS' ADMINISTRATION

Mr. Chairman and Members of the Committee:

I appreciate the opportunity to appear before you to discuss the activities of our Medical Inspector and Evaluation Office. The provision of high-quality health care to the veterans we serve is our highest goal. The impact on quality of care is an overriding concern for every decision that we make or action that we take. Although aspects of quality of care are involved in most of our daily activities, we do not really know how well we are doing until we evaluate that care and monitor various activities of each medical center. The Medical Inspector and Evaluation Office has two principal divisions (1) the Medical Inspector, and (2) Evaluation, that are primarily concerned with these monitoring and evaluative activities.

The Medical Inspector is primarily concerned with acting upon reported incidents of poor-quality care, and correcting situations that could result in poor-quality health care being delivered at a particular VA medical center. The primary function of the

Evaluation Division is to maintain the VA's Health Services Review Program (HSRO) which is the VA's primary medical quality assurance program. The HSRO program includes two principal components: the Systematic External Review Program (SERP) and the Systematic Internal Review Program (SIR).

Medical Inspector

The Medical Inspector Office was established on September 21, 1980, following hearings before this committee and the Administrator's approval of an agreement between the Chief Medical Director and the Inspector General.

Historically, each Region, until mid-1975, had at least one M.D. on its staff to review and correct issues of questionable quality in the delivery of clinical services. A functional reorganization was instituted at the operational level below the Associate Deputy Chief Medical Director in the summer of 1975. At that time, except for a "complaints" section, no central system was available for "troubleshooting" quality of care problems. The Office of Inspector General was created in 1978 and subsequently became aware that clinical problems could not be neatly listed under fraud, waste, and abuse. The result was an agreement with the Chief Medical Director to create a Medical Inspector Office within the Department of Medicine and Surgery (DM&S).

Concern was raised by this Committee about the ability of the office to be objective -- "fox in the hen house syndrome." The solution was to organize a Medical Inspector's Office within DM&S and for the Inspector General to exercise oversight over its activities. The Administrator approved the establishment of the office beginning September 21, 1980.

The office consists of three employees, a physician and two administrative and support persons. It is organizationally part of the Chief Medical Director/Deputy Chief Medical Director office as a staff element providing for direct access to the Chief Medical Director/Deputy Chief Medical Director, as needed, as well as being placed at a high enough level to exercise authority needed to fulfill its obligations. The office has deliberately been kept small, since human resources are available for use from throughout the system. Since 1980, the Medical Inspector has had good working relationships with all VA organizational elements including the Inspector General. The Medical Inspector's Office does not have line authority. The Associate Deputy Chief Medical Director and Regional Directors uniformly support recommendations for investigations and other actions.

To exercise oversight, the Inspector General has established a liaison with the Medical Inspector's office through which all communications flow. Regularly-scheduled meetings take place to discuss cases and problems, and frequent telephonic and other informal contact is maintained. All cases generated by the Medical Inspector are reported to the Inspector General and copies of all VA Medical Center investigations are routed to them. The relationship between the Medical Inspector's office and the Inspector General is excellent. They are mutually supportive and complement each other's area of interest. The mission of the office is to monitor the quality of care throughout the patient care system. This is done by several means:

Review of required patient incident reports and/or investigations mandated to be sent to our office.

Acceptance of allegations and complaints from any source such as the Inspector General.

United States Senators and Representatives.

Patients and Relatives.

Employees.

VA Central Office officials and offices.

Regions.

VA Medical Centers.

Veterans' Organizations.

Any others who wish to express their views and concerns.

These are processed in various ways--

Incidents and investigations are referred for comments to the appropriate VA Central Office services and then a judgment is made as to whether further action is required or whether the case can be closed. If further actions are required, a case file is opened and a procedure as below ensues.

All Others -- The material is reviewed and a judgment is made as to whether further action is required. Some problems may be clarified via the telephone, others require written clarification of facts. Sometimes an on-site visit may be deemed necessary. The composition of such a site visit team depends on the problem and may consist of one or more people. The team members may include the Medical Inspector and clinical or administrative specialists from VACO or anywhere in the field. When the report is finalized, recommendations are arrived at and implemented through the authority of the Regional Director. The actions may take the form of disciplinary actions, or programmatic changes, and are followed until we are satisfied with the result.

4.

In order to accomplish its mission, the Medical Inspector's office is heavily involved in coordinating and facilitating activities within VA Central Office. They have formal weekly meetings with each Region and the Associate Deputy Chief Medical Director to discuss ongoing activities, potential problem areas, resolution of old difficulties, and new issues. Informal meetings take place daily as needed. Meetings every two weeks are held with the major professional services, the Assistant Chief Medical Director for Professional Services, and with the Office of Personnel to discuss title 38 disciplinary actions. Since its creation the Medical Inspector's Office has caused manual changes to take place, tightened the requirements for reporting incidents and conducting investigations, and have instituted a semiannual report of all incidents by category and number from each VA medical center. The quality of the investigations into incidents involving patients and the clinical involvement in these investigations have improved tremendously in the last year or so. Both the facilities and VACO have come to regard these as learning tools that benefit the patient, quality of care, and management.

In the Fall of 1981, in order to facilitate the Medical Inspector in his responsibility to monitor quality of care, DM&S made the decision to place all elements involved in this function in one office. The Medical Inspector and Evaluation Office, the Investigations Office, previously a part of the Office of the Executive Assistant to the Chief Medical Director, and the Evaluation and Analysis Office were added to the Medical Inspector's Office. The Investigations Office served as a liaison between the IG Office of Investigations and DM&S. The Evaluation and Analysis Office served as liaison to the IG Office of Audit and the Joint Commission on Accreditation of Hospitals. It also was responsible for the Systematic External Review Program (SERP). These functions currently reside in the Medical Inspector and Evaluation Office. In addition, strong emphasis has been placed on the Health Service Review Organization (HSRO) Section.

Evaluation Division

To ensure that the medical care the veteran receives is of the highest quality, evaluation mechanisms are in place to continuously evaluate and monitor activities at each medical center. Some of these mechanisms are performed by each medical center through reviews of the quality and appropriateness of care provided, and the systematic review and monitoring of specific activities such as: qualifications of health care individuals providing care, quality of support services rendered, and the continuous review of some aspect of all services provided. Systematic evaluations are also performed by external groups such as: visits by a team of peer professionals to evaluate the quality of care being provided, periodic visits by program officials from VA Central Office to monitor ongoing activities, and reviews by bodies external to the agency such as Joint Commission on Accreditation of Hospitals and the College of American Pathologists. There are in fact approximately 40 reviewing bodies who either survey, audit, evaluate, or inspect our medical care facilities to ensure the provision of high-quality services.

The Evaluation Office has four sections: the HSRO Section, Patient Satisfaction Section, Reports Management Section, and SERP (Systematic External Review Program) Section. The Associate Director of the Evaluation Office is the liaison official to the Joint Commission on Accreditation of Hospitals and is responsible for negotiating the Department's survey contract which is approximately $1.5 million annually. He also serves as the Internal Control Officer for the Department in support of the President's initiative to eliminate waste, fraud, and abuse.

HSRO Section

The HSRO Section develops policies and procedures and provides guidance to field facilities in the area of quality assurance programs. These include such areas as the HSRO confidentiality regulations, and manual provisions which address specific elements of quality assurance such as: Blood Services Review, Pharmacy and Therapeutic Agents Review, Surgical Case Review, Infection Control, Credentialing and Delineation of Clinical Privileges, JCAH Accreditation, and the systematic internal and external review programs. This section is responsible for coordinating the Internal Control System for the Department as required by OMB Circular A-123. This system of internal controls is the President's initiative under Reform 88 for the elimination of waste, fraud, and abuse.

Patient Satisfaction Section

The Patient Satisfaction Section is responsible for biannually assessing patients' satisfaction with services that they receive from the VA. The surveys involve a questionnaire given to patients asking them to assess the care they received. The information from the questionnaires is computerized, analyzed and reports provided to each medical center regarding results of the survey. Facilities with significant findings are required to report to VA Central Office with an action plan for improvement of those areas where patients are less than fully satisfied with the care being received. The section monitors results of surveys and provides information to appropriate program officials in VA Central Office for action.

7.

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Reports Management Section

The Reports Management Section is responsible for coordinating responses to external reviews performed by the General Accounting Office, Joint Commission on Accreditation of Hospitals, Service Organization visits, VA's Program Planning and Evaluation, Inspector General Office of Audit, and Systematic External Review Program visits. Upon completion of a survey, audit or inspection, the report is submitted to this section and responses are requested from appropriate field and VA Central Office offices. This section monitors implementation of approved recommendations and provides management officials with the current status of corrective actions.

SERP Section

The Systematic External Review Program (SERP) is a peer review mechanism that evaluates the quality of patient care and the effectiveness of the Systematic Internal Review Program (SIR) in each VA medical facility. The fact that the review is external to the facility, yet internal to the Department allows it to be objective, yet tailored to meet the needs of the Department.

The SERP Section consists of team leaders who organize and lead a SERP survey team which visits the hospital to conduct a one-week survey. The survey teams are composed of four to ten team members who come from medical facilities similar to the one being surveyed. The team composition includes physicians, a dentist, a nurse and administrative personnel.

The SERP teams evaluate the medical center as a whole, addressing both patient care and support issues. Major emphasis is placed on clinical activities, including patient care

practices, medical record documentation, and quality assurance. Areas of special concern such as care of female veterans, agent orange activities, supervision of residents, POW programs, and OSHA requirements receive particular attention.

Specific objective criteria have been developed for the SERP review of each medical center by the individual medical services. These criteria are supplemented by JCAH criteria and professional judgment.

Upon return from the SERP survey, the SERP team leader briefs key VA Central Office officials concerning the findings. The survey report contains an adjective rating for each service, a brief description of the service, and a discussion of identified problems and recommendations. These reports are distributed to the medical facility and appropriate individuals within VACO for comments and corrective action.

SERP surveys are conducted on a variable cycle of not less than once every four years, depending on the facility's last "SERP Accreditation." The accreditation period may be for 1, 2, 3, or 4 years. By the end of this fiscal year, 104 of the 176 facilities will have been surveyed since the accreditation program was initiated in January 1982. While the budget requested for 1985 would provide for about 70 surveys, resource constraints over the last few years have only permitted approximately 40 surveys per year.

VAMC Systematic Internal Review (SIR) Program

Each Veterans Administration medical facility director is responsible for conducting a Systematic Internal Review (SIR) Program to ensure that the quality of care provided beneficiaries is of high quality and that this is evident through the ongoing monitoring of patient care activities. This program of systematic monitoring is the medical center's process for reviewing, evaluating and monitoring the quality and appropriateness of clinical and administrative services.

Systematic Internal Review is an ongoing system of activities supported by experienced medical staff and health professionals who have been trained in the philosophy and practical applications of quality assurance. These activities are linked organizationally through a variety of medical center committees which regularly evaluate patterns of care, patient outcomes, and resource utilization to provide a comprehensive picture of the extent to which patients are receiving quality care.

Continuous monitoring by medical staff and health care professionals of key clinical functions such as infection control, medical record review, surgical case review, and blood utilization review is the backbone of the Systematic Internal Review program.

Other components of the SIR program include utilization review, which is designed to assure that resources within the medical center are appropriately utilized; the credentialing and clinical privileging process which ensures that medical staff and health care practitioners or providers are qualified and perform only those procedures in which they are determined to be competent, as judged by their peers; and problem-focused health care evaluation which identifies and studies problems that may have an impact on the quality of patient care in order to pinpoint operational deficits and recommend corrective action, as necessary.

Mr. Chairman, this concludes our formal testimony. We will be glad to respond to any questions that you or members of the committee may have.

RESPONSE OF THE VETERANS' ADMINISTRATION TO WRITTEN QUESTIONS SUBMITTED BY HON. ALAN K. SIMPSON, CHAIRMAN OF THE SENATE COMMITTEE ON VETERANS' AFFAIRS

Question 1A.

In your testimony before the Committee concerning the resources available to the Office of Medical Inspector, you stated, "we have kept the office deliberately small, but it has available to it resources in terms of people from throughout our entire hospital system." However, certain important parts of the VA's quality assurance program involve specific functions performed by the Medical Inspector and Evaluation Office at the Central Office level, such as reviewing all patient incident reports, using Central Office team leaders to conduct SERP evaluations, responding to referrals received from the Inspector General's hot line, and overseeing the quality assurance peer reviews conducted by the individual medical centers.

Given that these activities are performed by the Office of Medical Inspector, what resources are needed, including the number of staff and funding, to optimally operate the Medical Inspector's Office?

Answer 1A.

At the present time, the present staff of the Medical Inspector's Office consists of one physician, one Health Science Officer, one Staff Assistant, and one Program Assistant, which is sufficient to handle the workload. The staff for the other functions of the Medical Inspector and Evaluation Office are also adequate. Future resource needs for this office will be provided as those needs are identified in consideration of other competing demands for these resources.

Question 1B.

Your written testimony stated that 70 SERP visits should be conducted each year to enable all facilities to be reviewed under this program once every 4 years, but that in the last few years no more than 40 surveys have been completed. What resources are needed, including the number of team leaders and travel funds, to optimally operate the SERP program?

Answer 1B.

The current staffing level of 7 FTE is adequate to complete 70 surveys annually provided this level is maintained with trained team leaders.

Travel funding of $504,000 would be required for this office to accomplish 70 SERP visits per year. Additional travel funding requested in the FY 85 President's Budget was intended to address this need.

Question 1C. In your testimony you stated that in your opinion the Office of Medical Inspector has been "dealt with fairly in the allocation of the funds that are available" in comparison to the allocation of travel funds to other program activities. A question was asked pertaining to a comparison of travel funds allocated for this and other programs. Please provide the Committee with a list of all Medical Administration programs, the corresponding travel funds requested for FY 1983, the levels of travel funding received, an explanation of how Medical Administration priorities are established, and where SERP surveys fall within this list of priorities.

Answer 1C. In FY 1983, requests for, and allocations of, employee travel (.007) funding in Medical Administration (Program 811) were as follows (corresponding Medical Care employee travel (870.007) figures are provided for completeness; office titles reflect program responsibilities):

DM&S Office (Programs)	Fiscal Year 1983			
	Medical Admin. ET		Medical Care ET	
	Request	Allocation	Request	Allocation
Chief Medical Director	$ 117,140	$ 85,874	$ 339,535	$ 246,314
Resource Management	62,300	49,237	22,385	22,385
Facility Engineering, Planning, & Construction	229,000	166,173	125,500	55,318
Management Support	25,000	21,138	342,100	96,853
Medical Inspector & Evaluation	164,000	102,795	505,000	218,601
Agent Orange Projects Ofc.	22,424	22,424	13,095	1,409
Associate Deputy Chief Medical Director	275,000	262,162	929,030	929,030
Medical Information Resource Management Ofc.	140,000	85,873	380,900	335,000

Professional Services	168,277	146,003	243,620	193,288
Administration	328,273	183,891	746,256	327,414
Academic Affairs	117,920	67,931	148,400	44,946
Research & Development	103,350	55,030	50,000	6,183
Dentistry	40,900	35,976	40,100	12,633
Extended Care	46,507	31,191	86,697	35,799
Program Analysis & Development	144,915	75,302	147,600	134,458
TOTAL	$1,985,006	$1,391,000	$4,120,218	$2,659,631

Requests for employee travel funding in FY 1983 were arrayed against the anticipated Congressional limitation. A single priority listing of all requests was not produced. However, DM&S staff reviewed all requests and recommended initial funding levels to the Associate Deputy Chief Medical Director. Ultimately, funding levels were approved by the Deputy Chief Medical Director, and employee travel funding was then distributed to DM&S offices.

The Department of Medicine & Surgery recognizes that SERP surveys are a critical factor in maintaining the quality of VA health care delivery. However, as the above figures reveal, there is a gulf between requests and allocations for many significant DM&S programs. Lower than requested employee travel funding levels for the SERP program do not indicate the Department's lack of concern for monitoring the quality of care. Rather, the figures reveal tremendous competition for scarce resources. The FY 85 President's Budget contains additional employee travel funding that will address this need.

Question 2. What specific risk management policies have you set up for quality assurance monitoring which are pro-active, that is, methods that are set up specifically to prevent quality of care problems by detecting a problem which if not acted upon could contribute to a more serious problem or incident occurring at a later time?

Answer 2. Patient Injury Control, which consists of the initiation of VA Form 10-2633, "Report of Special Incident Involving a Beneficiary," and the subsequent recording and analyzing of the incident, is an ongoing monitoring system in each medical center. Within each facility the Systematic Internal Review Program (SIR) periodically reviews areas of possible problems, determines if a problem exists, or if procedures, etc., can be improved. If problems are detected, solutions are developed and implemented. Under A 123, each Service in each facility is required to do vulnerability assessments on areas of possible risk. A list of these areas is submitted to VACO for review. If it has been determined by the medical center that the area has high vulnerability, then the medical center is required to state what corrective/preventive actions have been taken. Twice a year each medical center is

required to submit to VACO a count of the total number of incidents that have occurred. This count is broken down by type of incident; such as falls, medication errors, and attempted suicides. This allows for a monitoring by medical center in VACO and systematic identification of areas that may require further investigation or identification of areas in which there is a need to develop educational courses. In addition, any investigation that is conducted into an incident involving a patient is submitted in its entirety to VACO for review. This serves as an excellent monitor of internal happenings within the individual medical center.

Question 3A. What specific risk management policies do you have or are you in the process of developing which address the trends in quality of care problems that have already occurred in a particular medical specialty, procedure, medical center, and/or by an individual physician?

Answer 3A. The semiannual report of incidents that occur in each facility is now being kept in a word processing system. The file is broken down by medical center, by District, and by Region. The system is capable of sorting by type of incident, by facilities in which that

incident occurs, by facilities having the incident occur over "x" number of times, etc. As the data base grows, the office will be able to do some trending on incidents. The program people within Professional Services monitor occurrence of incident mobidity, mortality, etc., for their areas of responsibility. The Medical Inspector's Office meets regularly with the various Services to exchange concerns, information, and ideas. Within the Medical Inspector and Evaluation Office, in addition to the computerized External Review Management Information System (ERMIS) there is a debriefing given to the Medical Inspector's Office by SERP team leaders on their return to inform the Medical Inspector of problems identified.

Question 3B. Do you use mortality rates as performance standards for physician providers, and if so, is the data collected by facility, mortality event, and by provider? Is the data analyzed on an annual basis and are the results of the analysis provided to the Chief Medical Director for review? Do you use complication rates as a measure of performance?

Answer 3B. Neither mortality rates nor complication rates are used as performance standards for physician providers. If outlying trends of either circumstance were identified, it would be the responsibility of the Chief of Staff to take appropriate action.

Question 3C. The VA's 1984 annual report on special pay for physicians and dentists indicated that 38 percent of full-time VA physicians are not Board Certified and 27 percent of part-time VA physicians are not Board Certified. What, if any, impact might this have on the ability of VA physicians to provide quality care?

Answer 3C. We anticipate no lessening of our ability to provide appropriate and quality care to veterans.

The figures given in the 1984 annual report indicate that the majority of VA physicians (62% of full-time and 73% of part-time) are Board Certified. Board Certification reflects the fact that a physician has met certain minimum standards of training and experience. The implication is that Board Certified physicians will be more clinically effective then physicians who are not Board Certified. However, many of the physicians who are not Board Certified are Board Eligible. This means that they also possess, at least, the minimum qualifications in terms of training and experience as their counterparts who are certified. Not being Board Certified, therefore, does not necessarily imply that such a physician is less medically competent.

One of the continual efforts by the VA to provide improved quality of care is by hiring highly competent physicians. Whereas, it may be a desirable goal to hire only Board Certified physicians, it is an unrealistic goal. The special pay for the more qualified physicians has assisted immeasurably in the recruitment and retention in a very competitive market.

The appointment of Board Certified physicians as chief of clinical services and the affiliation with medical schools of most of our VA medical centers enhance the ability of the VA to improve its delivery of quality care to veterans.

Question 4A.

A question was asked at the hearing concerning malpractice suits filed with the VA. You stated that in fiscal year 1983, 956 suits were filed of which 815 were either settled or denied and that 895 claims are now pending within the VA.

Please provide the Committee with the following additional information with respect to malpractice claims: How many of the 815 claims which were resolved were settled and how many were denied? Please provide a list of the numbers and kinds of cases that were filed most frequently.

Answer 4A. In Fiscal Year 1983, 956 medical malpractice claims were filed with the VA and 747 were either settled or denied; settlements being reached on 221 claims and 526 claims being

denied. At the end of FY 1983, 895 claims remained pending. No statistics are maintained by the VA as to the types of medical malpractice claims and the frequency of various types of claims.

In addition to medical malpractice claims, there were 229 suits filed in FY 1983 alleging medical malpractice at VA facilities. Eighty-three (83) such suits were dismissed, 17 went to judgment in favor of the person suing, and 35 resulted in judgments for the government.

Question 4B. Is there any systematic mechanism used by the Medical Inspector to collect and analyze data on malpractice claims that are filed in the individual medical centers and at the Central Office level? If so, is the data analyzed and used to serve as an indicator or possible evidence of quality of care problems or trends in specific services or centers, in the system as a whole, or in cases of specific health care professionals?

Answer 4B. Currently, there is no systematic mechanism used by the Medical Inspector to collect and analyze data on malpractice claims. This office is working with the Office of the General Counsel to set up such a system. It is anticipated that such a system will be functional by the beginning of Fiscal Year 1985.

Question 4C. Are patient incidents reports systematically analyzed to determine trends or indicators of quality care problems, and

if so, by whom and how often. If not, why not?

Answer 4C. Yes. They are reviewed on an on-going basis by the Medical Inspector. In addition, each Health Systems Specialist within each Region is given quarterly, a list of all incidents and investigations that have been reported to VACO by facility for each of the facilities with which he deals. The semiannual report which gives a breakdown of incidents counts is reported to VACO and is also supplied to each DM&S Regional Office. Each Service within Professional Services receives those investigations that fall within their sphere of influence to review and comment upon. They, too, receive copies of the semiannual incident counts for those incidents that occur within their program area. Such reports are also analyzed by each medical center as part of its patient injury control program and continuous monitoring.

Question 4D. Are malpractice claims systematically compared with data collected on patient incidents reports at individual medical centers to determine trends in quality of care programs? If so, please provide the results of the most recent reviews. If not, why not?

Answer 4D. No. Up to now we have not had the capability to do so.

Question 5A.

In your testimony you stated that the systematic internal review program is the responsibility of each medical facility director. Regulations prescribed on October 22, 1982, concerning the Health Services Review Organization (HSRO) require each VA medical facility director to authorize an existing committee or subcommittee to integrate and coordinate HSRO activities and to develop a written plan which establishes responsibilities, defines policy and describes the procedures and mechanisms necessary to maintain an effective quality assurance program.

What specific activities are conducted by the Medical Inspector to ensure that each medical center has a quality assurance committee and plan and that the mandatory functions set forth in the regulations are performed.

Answer 5A. SERP surveyors review the HSRO activities during the survey process and evaluate the facility's HSRO program. The HSRO Section of MI&EO monitors this bi-annually by requesting a copy of each VAMC's HSRO plan. The SERP team leader reports to the HSRO Section on the results of the evaluation of a facility's HSRO program and plan. Based on the results of the evaluation the HSRO Section may consult with the facility and provide information relative to methodologies for improving the HSRO Program if there are significant problems. JCAH, at the time of its inspection, checks to insure that a quality assurance program is in effect and the regulations are being followed. It should be noted that the majority of

regulations in this area are also requirements of JCAH or other external evaluation groups.

Question 5B. You have stated that the SERP mechanism evaluates the effectiveness of the internal review program in each of the VA medical facilities. However, these reviews often occur only once every 4 years. The regulations on the HSRO program require that an annual review be conducted of the individual medical facilities programs. Are such reviews conducted on an annual basis and if so, by whom? What activities are conducted by the medical Inspector to insure that such reviews occur?

Answer 5B. Yes. These reviews are conducted by the HSRO/QA Coordinator who then reports to the Chief of Staff and the Director. This is frequently done through the Clinical Executive Board. At the time of SERP visits, the minutes of the Quality Assurance Committee or other appropriate documentation is reviewed.

Question 6A. In your testimony, you stated that in your opinion there are certain advantages to having the Medical Inspector's Office within the Department of Medicine and Surgery. What do you consider to be the major disadvantages of this arrangement?

Answer 6A. No real disadvantage has been identified.

Question 6B. In response to a question at the hearing concerning whether only physicians have the capability of monitoring other physicians, you stated that there are a number of advantages to that particular procedure. With respect to investigations of patient care incidents, Dr. Lindsay, Medical Inspector, stated, "Any physician, nurse, administrative person in the system is available to go out and make the site visit if required." How do you reconcile the differences between these two views?

Answer 6B. Not all reviews deal with review of physicians. Visits may have to do with other health care providers, such as nurses, or the visit may deal with administrative personnel, or the functioning of a total service. A person who is knowledgeable in the area to be examined is used for the site visit.

Question 6C. A suggestion has been made to move the Medical Inspector's Office from the Department of Medicine and Surgery in order to enhance its credibility and respond to the charge of the "fox watching the hen house." What do you see as the possible advantages of such a move?

Answer 6C. I see no advantages to such a move. The Inspector General testified at the June 6 hearing that we have a very cooperative working relationship. Matters that should be are referred both directions from our two offices. To my knowledge there have been no instances where the credibility of the Medical Inspector's Office has been called to question.

Question 6D. **What is your view of the suggestion to have the Inspector General rely on the advice of outside physician consultants in matters pertaining to his oversight responsibilites with respect to the Office of Medical Inspector?**

Answer 6D. It is not felt to be necessary. The Medical Inspector's Office has, I believe, adequately demonstrated that it has available any or all clinical resources of whatever discipline to review cases. No suggestion of shrinking from making hard decisions and/or recommendations concerning the adequacy of care or conduct of physicians has been noted. If, in the process of oversight, areas of concern arise in the Office of the Inspector General, these can be resolved by consultation with the Medical Inspector, and have been to the satisfaction of all.

Question 7A.

According to the General Accounting Office, the Medical Inspector conducted 43 investigations of patient suicides and suicide attempts in fiscal year 1983.

What accounts for such a large number of these cases and what specific preventive measures have you taken or have you planned for all psychiatric units and medical centers to prevent such events from occurring?

Answer 7A.

Each suicide or suicide attempt is one more than is desirable. The overall suicide rate in the United States as published by the United States Center for Suicide Statistics for 1978 (latest figures) was 12.5 per one-hundred thousand population, and 19.0 per one-hundred thousand for the total male population. Based on the national annual frequency of suicides among the male population in the United States, one would have expected an annual frequency of 570 suicides throughout the VA medical care system. Therefore, the annual frequency of suicides within the VA health care system was significantly less than would have been expected. Each of these suicidal behavioral incidents was investigated.

The absolute predictability or prevention of suicides or suicidal attempts cannot be determined. However, the VA has for several years

conducted educational and training programs to increase the skills of employees at each facility pertaining to the identification, prevention, treatment and management of suicidal behavior. Regional Medical Education Centers have developed programs for trainees from each facility. They are taught how to develop specific appropriate action plans for dealing with special problems; to analyze attitudes; the importance of communicating information to other team members; to discuss pertinent legal and administrative issues regarding patient's rights and to know key factors in creating a proper physical setting for patients who are suicidal. Upon return to their respective facilities, these trainees are expected to implement these concepts in training of local interdisciplinary treatment teams. Each medical center has been encouraged to develop a Mental Health Council, consisting of interdisciplinary health care workers, whose primary function is to develop and evaluate data and general treatment programs for psychiatric patients. VACO has issued regulations and directives to serve as guides in gathering data for reporting and investigating incidences of suicides and attempted suicides. For example, the directions given in Circular 10-84-81, dated May 22, 1983 "Monitoring

of Suicides and Attempted Suicides within the Veterans Administration System," VA Form 10-0046; and in the Department of Medicine and Surgery Supplement MP-1, Part 1, change 38, chapter 2, entitled "Investigation and Security Policies," Section A "Investigations," state that all suicides and serious suicidal attempts must be reported to the appropriate Regional Director immediately either by telephone or teletype, to be followed later by a report of the investigation of of incident. VACO has also issued directives and guides on the treatment of suicidal patients. These include Circular 10-83-53, dated March 23, 1983 (reissued April 10, 1984), "The Prevention and Management of Disturbed Behavior: Violent, Homicidal and Suicidal Patients; and Mental Health and Behavioral Sciences Service Program Guide, G-15, M-2, Part X, dated March 13, 1983, "Management of the Violent and Suicidal Patient." Treatment teams at each facility are encouraged to conduct a psychological autopsy following an attempted or accomplished suicide. The primary purpose of this psychological autopsy is to gain an understanding of the psychological circumstances in which suicide victims met their death, or under which the attempts were made.

Question 7B. **Are there specific policies requiring site visits by an investigating team when trends such as patient suicides and suicide attempts are beginning to develop?**

Answer 7B. In reviewing the number of suicides and suicide attempts (43 for Fiscal Year 1983 according to the GAO investigation) one should keep in mind that in Fiscal Year 1983 the VA treated as inpatients on Psychiatric Services 177,575 veterans for a total of 7,372,125 bed days of care. The other fact that should be kept in mind is that the Medical Inspector's Office receives information on both inpatients and outpatients and that the figure appears small compared with statistics concerning the population at large. There are no specific policies requiring site visits by an investigating team based on the number of suicides or suicide attempts. Each suicide is reviewed and a decision is made, based on the circumstances of the case, whether it is necessary to send a team to do a site visit. Central Office has, through its Central Research Unit conducted research pertaining to suicidal behavior and has an ongoing program for monitoring suicide behavior among patients in the VA health care system.

Question 7C. How many site visits were made to investigate these incidents?

Answer 7C. Three.

Question 8A.

A recent GAO review of a sample of 38 patient care incidents found that the Medical Inspector had not been notified in 3 of these incidents until over a month after they occurred. These incidents included the following:

--A psychiatric patient from the VA Medical Center at Augusta, Georgia, was killed in an accident on February 24, 1984. The Medical Inspector was not notified of this incident until he received the Medical Center's Board of Investigation report on May 1, 1984.

--A patient at the Brooklyn VA Medical Center attempted suicide on February 3, 1984, and the Medical Inspector did not receive notification of this incident until May 11, 1984.

--A nursing assistant at Olin E. Teague VA Medical Center in Temple, Texas, abused a patient April 6, 1984, and this incident was not reported to the Medical Inspector until May 8, 1984.

What length of time is considered appropriate in order to comply with the regulation requiring medical centers to "immediately" report patient care incidents?

Answer 8A. The medical facility is allowed time to develop or collect all the necessary facts on a case prior to notifying VA Central Office. It may well be that an incident involving a patient occurs and the staff involved is busy with the patient for 6 or 8 hours before they can break away from the patient's care in order to document what occurred. Generally, if possible, it is felt that incidents of this nature should be reported within one working day. Obviously, if an incident occurs on the weekend there would be no one in VACO to receive the report until Monday morning.

Question 8B. What action is taken, and by whom, when medical centers do not comply with this reporting requirement?

Answer 8B. The Office of the Medical Inspector reminds the Director of the facility about the reporting requirements. This letter is sent through the Regional Director. If the problem persists, the Regional Director reinforces the need to meet the reporting requirements and takes whatever action he deems appropriate.

Question 8C. Do you consider it appropriate to require simultaneous notification of the appropriate Regional Director and the Medical Inspector for potentially serious quality of care problems?

Answer 8C. The report that is sent to notify the Medical Inspector of potentially serious quality of care problems is sent through the Regional Director so, in fact, one notification is sent to VACO. It is felt that it is appropriate to notify the office with "line" responsibility and the office that has the programmatic responsibility.

Question 8D. **What policies and procedures have been established to insure that all incidents are being reported?**

Answer 8D. At the time of the SERP visit, the folder of incident reports is checked to make sure that incidents that require investigations did have the investigations done and that they were reported to VACO. Some incidents, such as complications in the Cardiac Catherization Laboratory, require reporting to VACO Medical Service as well as the Medical Inspector's Office. There is ongoing communication between the two offices to insure that both offices receive the appropriate notification. When the semiannual report is received, the counts of the incidents are cross-checked with the log of the individual incidents that have been reported previously. In addition, the HSRO Coordinators at the medical centers monitor the incidents that are reported within the medical center to insure that the appropriate incidents as described in DM&S Supplement MP-1, Part I, Change 38, are reported to VACO. Within each medical center, there is ongoing training for personnel dealing with what incidents need to be reported, to whom they should be reported, and how they should be reported.

Question 9A. According to the General Accounting Office, not all complaints involving quality of care problems are routed directly to the VA Medical Inspector. In some instances letters are routed through the VACO's Communications and Inquiries Office to DM&S's Office of Professional Services where they are treated as inquiries.

Why aren't all letters alleging quality of care issues sent directly to the Medical Inspector?

Answer 9A. Correspondence received in the Department alleging quality of care discrepancies are routed to Professional Services for review and investigation of the allegations. Professional Services will then have the appropriate medical specialty review the necessary records and determine if the treatment prescribed was appropriate. Should this review process reveal that a potential quality of care issue exists, the response to the inquiry is then sent to the Medical Inspector for concurrence and necessary action. The vast majority of such correspondence are not quality of care issues but rather misunderstandings of procedures and medical practices on the part of the writer.

Question 9B. What is the total number of letters concerning quality of care problems received in Central Office each month? How many of these eventually get reviewed by the Medical Inspector?

Answer 9B. During the first three months of 1984, Professional Services responded to an average of 56 inquiries per month. Of these, there were approximately 3 referrals to the Medical Inspector's Office as potential quality of care issues during this same time period. It should be noted that not all of the incoming referred to Professional Services alleged quality of care discrepencies. The majority address various program areas under the jurisdiction of Professional Services such as Prosthetics, Blind Rehabilitation, Recreation, Chaplains, etc.

Question 10A. What specific policies and guidelines have been established to aid medical centers to follow in conducting their own medical investigations?

Answer 10A. In doing investigations, the Medical facilities are required to have three people on the Board of Investigation, and at least one of the people must be of the clinical discipline that is involved in the case. Security Service in DM&S has put out a booklet entited, "A Guide to Administrative Investigations," for use by hospitals.

Question 10B. Does DM&S conduct training on how medical centers should conduct medical investigations?

Answer 10B. Currently, DM&S does not conduct training on how medical centers should conduct investigations. Plans are underway to offer such training in Fiscal Year 1985. Some of the medical centers have developed their own courses.

Question 10C. How should smaller VA medical centers, which have limited medical personnel resources, conduct medical investigations?

Answer 10C. The smaller medical centers should conduct their investigations in the same manner as other medical centers. If they have need to have additional personnel or expertise they may request that personnel be detailed from another facility for the investigation.

Question 11A.

A General Accounting Office review of investigation reports received during the week of May 7-11, 1984, found that 5 of 13 reports were not received within the required 30 days. Another GAO sample found that the Medical Inspector either sought clarification, requested additional information, or sent a team to the VAMC's for further investigation.

What specific mechanisms have been set up to monitor medical center's compliance with the 30-day reporting requirements.

Answer 11A. At such time as the investigation is reviewed by the Office of the Medical Inspector compliance with the 30-day reporting requirement is checked.

Question 11B. What steps are taken to improve compliance?

Answer 11B. Medical centers have been reminded on the CMD Hotline, on the Regional Director Hotline, in the HSRO Newsletter, and by this office. The various educational courses being offered in Quality Assurance will stress these deadlines to the HSRO coordinators and others. Certainly, implementation of A 123 and the increasing emphasis on Quality Assurance by JCAH will place additional pressure on the hospitals to do the investigations in a timely manner so that any necessary corrective actions may be taken.

Question 11C. What specific policies and guidelines have been established to aid medical centers in preparing investigation reports?

Answer 11C. The guidelines developed are found in "A Guide for Conducting Administrative

Investigations." This gives them a format and a description of the information that should be contained in the various sections of the report.

Question 12A. What specific actions are the regional health systems specialists required to perform in order to monitor the implementation status of recommendations made by investigation teams and ensure that such implementation does occur?

Answer 12A. The regional Health System Specialists are responsible for monitoring and evaluating all audits conducted at field facilities. Basically, the health system specialist (1) assures that given health care facilities prepare implementation plans to be followed in correcting cited deficiencies, (2) reviews interim reports and action plans submitted by the facility, (3) conducts periodic site visits to field facilities to verify the implementation of corrective management actions and, (4) reviews reports received from other accrediting/external reviewers, i.e., JCAH, for related or similar deficiencies. In all of the above functions, the Health System Specialist exercises a management awareness of atypical operational/ management situations and advises his/her respective regional director and the medical inspector's office of those situations, attendant recommendations, and action plans which require more indepth application of the aforementioned functions, e.g., special focused site visit to verify implementation of an unresolved recommendation.

Question 12B. How are issues resolved when a medical center does not concur with the recommendations of the inspection team?

Answer 12B. When the medical center does not concur with the recommendations of the inspection team, it submits its reasons for nonconcurrence through the Regional Director to the Medical Inspector. The Medical Inspector then reviews the response and discusses the parts where there is disagreement with the Regional Director and his staff. If agreement still cannot be reached, the Medical Inspector then discusses the issues with the Associate Deputy Chief Medical Director until resolution occurs.

Question 12C. How are the regional health systems specialists able to adequately monitor implementation of recommendations dealing with needed medical improvements if they are not physicians?

Answer 12C. Just as administrative staff in VA medical centers rely on appropriate clinical staff in matters requiring medical opinion, so do regional Health System Specialists seek the advice of professional program staff regarding medical matters. Clinical and administrative staff are both organizationally aligned under the Associate Deputy Chief Medical Director and work in concert in dealing with recommendations regarding medical improvements. In addition, regional Health System Specialists work closely with the Medical Inspector and Evaluation Office to assure that the highest standards of medical care are maintained. In other words, Health System Specialists are managers. They rely and draw upon multiple staff resources, including physicians who provide clinical expertise, to complement their management responsibilities.

Question 12D. What role does the Medical Inspector play in ensuring that regional health systems specialists are monitoring the implementation of recommendations and that the recommendations is in fact implemented?

Answer 12D. The Medical Inspector formally meets with the Health Systems Specialists of each Region once a week. At that time, pending issues, new issues, and the status of recommendations are discussed. At the time SERP teams or program people from Professional Services visit the facility they are asked to review the outcome of the implementation of the recommendations.

Question 12E. Are the recommendations made by the investigation teams incorporated into the computerized External Review Management Information System (ERMIS) and if not, why not?

Answer 12E. No. ERMIS deals with general recommendations and/or deficiencies for a Service or the whole facility. The recommendations made by an investigation team are quite specific, often involve personnel and may be covered by 38 U.S.C. 3305, confidentiality regulations. There are no safeguards within ERMIS to protect this type of information. In addition, there is wide distribution of ERMIS and it is felt that it is inappropriate that Medical Inspector cases receive that type of distribution.

Question 13A. What steps are taken, and by whom, to ensure that SERP recommendations are implemented and that subsequent reviews do not reveal deficiencies which were reported in previous reviews?

Answer 13A. A Chief Medical Director's Letter is published annually which directs emphasis to ensuring that accepted recommendations are implemented and deficiencies are not identified as a repeat deficiency during a subsequent survey. Reports and action plans received from each medical facility are forwarded to the Regional Directors for appropriate action. Regional Directors are responsible for ensuring that recommendations are implemented.

Question 13B. What specific documentation is gathered, and by whom, to verify that SERP recommendations are implemented?

Answer 13B. Action plans are requested from each VA medical facility for each deficiency identified. Action plans are then provided to the Regional Directors for review and appropriate action if necessary. The SERP Team Leaders follow-up on implementation of significant recommendations made as a result of a survey by a site visit or a written progress report from the facility within specified timeframes.

Question 14. **What specific quality assurance activities or programs are used to ensure quality of care in VA nursing homes?**

Answer 14. The Regional Medical Education Centers (RMEC's) provide quality assurance educational programs for long term care in response to the needs of the Department. The SERP teams evaluate the quality of care in VA nursing homes by applying the Nursing Home Care SCEM (Standards, Criteria, Evaluative Algorithms, Measurement) during the survey process. The Nursing Home Care SCEM contains the standards by which nursing home care is evaluated. The Joint Commission on Accreditation of Hospitals (JCAH) evaluates the quality of medical care provided by VA facilities with specific standards for long term care.

RESPONSE OF THE VETERANS' ADMINISTRATION TO WRITTEN QUESTIONS SUBMITTED BY HON. ALAN CRANSTON, RANKING MINORITY MEMBER OF THE SENATE COMMITTEE ON VETERANS' AFFAIRS

Questions 1A and 1B. What is the Medical Inspector's (MI) role with reference to malpractice claims involving VA personnel?

Specifically, does the MI review malpractice claims in order to evaluate proposed action in such claims, including proposed corrective actions, and, in those cases in which malpractice is found or a settlement entered into, any proposed disciplinary actions?

Answers 1A and 1B. The Medical Inspector has not had a role in reference to malpractice claims involving VA personnel. Presently, there exists no mechanism to provide the MI with the information on claims. Negotiations have been entered into with the General Counsel to provide the MI with sufficient new claim information from the District Counsels at the time of filing that appropriate reviews can be made with a view to ascertain whether problems exist, whether they are being properly addressed, and whether disciplinary action is taken when required.

Question 2. When a reported problem involves both quality of care issues as well as other issues that fall under the purview of the Inspector General (IG), how are the investigations coordinated?

Answer 2. Coordination is performed using the telephone or meeting in person, depending on the complexity of the issue. The discussion then determines who should

examine what, how the investigation is to take place, how many should be assigned, whether they will work together or separately, etc. When the MI's portion is completed, the report is sent to the IG, who always has the lead in combined investigations, for his review and concurrence.

Question 3A.

On page 2 of the VA's statement, it is noted that "each (DM&S) Region, until mid-1975, had at least one M.D. on its staff to review and correct issues of questionable quality in the delivery of clinical services."

Did these physicians carry out investigations themselves?

Answer 3A. Many of the investigations were carried out by those physicians, others were assigned to members of the VA Central Office Professional Services, or physicians were assigned from field stations.

Question 3B. To whom did they report on their findings and the success of their efforts?

Answer 3B. They reported back to their Regional Directors and, when appropriate, to the Associate Deputy Chief Medical Director, Deputy Chief Medical Director, or the Chief Medical Director. The efforts were generally successful but depended entirely

on the individual Regional Director's attitudes about the issues. There was no central direction and therefore no uniformity in applying or enforcing standards and regulations.

Question 3C. Has any consideration been given to reestablishing such positions?

Answer 3C. When the Regions were reestablished by the then Chief Medical Director, James Crutcher, M.D., in 1978, consideration was given to having either the Director or Deputy be an M.D. The decision was made to not place physicians in such positions because of the inability to provide them with the Physician's Bonus.

Question 3D. On page 4 of his testimony, Dr. Clinton of the Office of the Assistant Secretary for Defense (Health Affairs), noted that, in the near future, all DOD medical care facilities "will have at least one full-time person to assume the day-to-day responsibilities of coordinating quality assurance activities undertaken by the many staff persons of the facility." If this is a good idea for the much smaller Department of Defense hospitals, would it not be a good idea for each VA health care facility?

Answer 3D. It is a good idea, and we are pleased that DOD plans to implement it. We are happy to report that the VA first introduced this concept in March of 1977 when it was suggested that each VAMC might designate someone to fulfill this role. This

position became mandatory in 1982. In the interim, virtually all VAMC's did assign someone as HSRO Coordinator, the term used by DM&S for the person who coordinates quality assurance activities within a medical facility. Some of the larger institutions have 4 to 5 people assigned to that office, and in at least one location, there is a full-time physician assuming that responsibility.

Question 4.

In two recent cases that have come to my attention, physicians hired by the VA had, at the time they were hired, restricted licenses from state licensing authorities or had previously lost their licenses. In both cases, subsequent public disclosure in the press of the facts surrounding the status of these physicians' licenses resulted in significant adverse publicity for the agency in the two geographic areas involved, Detroit and Los Angeles area, and great misfortune and personal trauma for the physicians involved as well as their families.

Comment: In the case referred to from the Los Angeles area, there was an erroneous allegation made by a staff physician that the physician in question possessed a restricted license. He did in fact have an unrestricted license. His license had been revoked, the revocation was stayed, and he was on probation but no restrictions on his license had been imposed. In the case from Detroit, the physician held licenses in two states. The Michigan license restricted him to institutional practice and the medical

center erred in employing him on that basis. When faced with discharge, he presented the unrestricted license from Colorado.

Question 4A. What is the present guidance provided to field facilities relating to the employment of physicians or other health care personnel with restricted licenses?

Answer 4A. The guidance is clear -- 38 U.S.C., 4105A(a)(1), states that applicants must possess the proper medical degree and a license to practice medicine in any state or District of Columbia. DM&S Supplement, MP-5, Part II, Chapter 2, paragraph 2.04h further requires that the license presented be unrestricted.

Question 4B. It seems to me that one possible approach to this issue would be to require Central Office concurrence on any local decision to hire an individual with a restricted license. Please comment on this proposal.

Answer 4B. Regulations forbid the hiring of a physician who presents a restricted license.

Question 5. In cases in which quality of care issues are raised which involve non-physicians (e.g., nurses, pharmacists, or other non-physician employees in DM&S), does the MI utilize individuals from the same profession or occupation to carry out the investigation?

Answer 5. Health care professionals of all disciplines are used as appropriate for investigations and opinions in order that a true peer review may take place and that the judgment is rendered by those most likely to be experts in the field. When investigations are performed in the field, DM&S Supplement MP-1, Part I, Change 38, paragraph 3.a., states that: ". . . the Director will appoint a board (a minimum of three people) having appropriate professional representation to develop the facts and furnish a complete report to include recommendations. Appropriate professional representation means that if Nursing Service personnel are an integral part of the incident, then a registered nurse should be on the Board of Investigation . . ."

Question 6A.

With reference to the issue, which Senator Simpson raised during the hearing, regarding which complaints received by the MI are selected for investigation through a site visit:

Please provide information for each year since the MI was established on the number of complaints received by the MI in each year, the number of investigations opened, the number involving site visits (further broken down by the number of site visits carried out by the MI and the number of field personnel) and the cost of travel associated with site visits.

Answer 6A.

	FY 1980	FY 1981	FY 1982	FY 1983	FY 1984
Complaints Received	33	102	91	113	62
Investigations Opened	28	97	91	112	62
Resulted in Site Visit	1	15	5	5	12
Visit Carried Out By:					
Medical Inspector		10	4	2	6
Other VACO	1	6		3	2
Field Personnel	1	19	6	5	17
Cost	$250	15373	4632	6992	18359

(It should be noted that this chart does not include the 1,000 or so investigations that are reviewed each year but deals specifically with complaints.)

Questions 6B and 6C.

How is a decision made on whether a site visit is appropriate?

Does any other office or official evaluate decisions to conduct or not conduct site visits in specific cases?

Answers 6B and 6C.

The need for a site visit is based on the seriousness and complexity of the problem. For example, several suicides over a relatively short period of time at

the same VAMC might trigger a site visit or one suicide if the investigation suggested incompetence and laxity in several services. Decisions for a site visit to take place are coordinated with the Region and, as needed, Associate Deputy Chief Medical Director, Deputy Chief Medical Director, or Chief Medical Director. In addition, site visits may be made as a result of a request from the Director who feels he needs an outside opinion, the Regional Director, or other VACO management who feel the need for an outside review of a service/personnel, specific issues, etc., or from Members of Congress.

Question 6D(i). When a decision is made to utilize field personnel for a site visit, how are such individuals chosen?

Answer 6D(i). Field personnel are chosen from a roster maintained by the MI covering the various specialties. The persons on this roster are individuals either known to and previously used by the MI or who have been recommended as not only having expertise in his or her field but also the ability to produce a thorough and objective

assessment. To date, the site visitors have shown no reluctance in writing straightforward, objective reports that contain tough recommendations. There has been no attempt to soft pedal a problem or to shy away from the appropriate recommendations because of the impact they might have on fellow professionals. Their individual expertise in the areas to be investigated are considered, as well as their location in reference to the VAMC being looked at. Team composition is coordinated with Chiefs of Services, Regions, and Associate Deputy Chief Medical Director, as necessary.

Question 6D(ii). Do such personnel receive any training or special preparation to carry out these investigations?

Answer 6D(ii). Such personnel are thoroughly briefed on their missions, given all material available, and guidance as to how to proceed. Plans have been laid to provide training in investigations.

Question 7.

On pages 4 and 5 of his testimony, Dr. Clinton, of the Office of the Assistant Secretary of Defense (Health Affairs), discussed a DOD directive entitled "Dissemination of Information on Medical Officers" which requires each Military Department to report to the Federation of State Medical Boards (FSMB) with respect to those DOD medical officers "whose clinical practice privileges are suspended, limited or withdrawn at the time they are separated from the service." Please describe VA policy on this issue and provide copies of any guidance provided to the field on the issue and information on the number of reports made by the VA to the FSMB on such matters in each of the past five fiscal years.

Answer 7.

We are pleased to attach copies of the Interim Issues dealing with the issue. They provide for the notification of the appropriate State Licensing Board following the termination of employment of any licensed health care provider, not just physicians, if it is felt that their actions might represent a danger to the population at large. The VAMC Director requests permission for such notification in writing from the MI and the Associate Deputy Chief Medical Director. After concurrence by the General Counsel, permission may be granted.

VETERANS ADMINISTRATION
Washington, D.C. 20420

March 23, 1983

INTERIM ISSUE 00-82-7
Supplement No. 1

A. BASIC ADMINISTRATIVE ISSUE AFFECTED: MP-5, Part I, Chapter 297.

B. OTHER ISSUES AFFECTED: None.

C. REASON FOR ISSUE: To extend the rescission date of Interim Issue 00-82-7 and clarify the procedures.

D. TEXT OF ISSUE: Interim Issue 00-82-7, VA Manual MP-5, Part I, Chapter 297, is modified as follows:

1. Page 1, paragraph C.: Line 8, insert:

"For purposes of this Interim Issue, the terms "terminated employee" or "terminated health care professional employee" refer to any former employees whose employment required the maintenance of a current license or registration and whose professional medical practice so significantly failed to conform to generally accepted standards of medical professional practice as to raise reasonable concern for the safety of private sector patients. This VA disclosure policy applies to any former VA medical professional, including one who has been discharged, separated, or terminated by the VA, or, who has resigned or retired."

2. Page 3, paragraph D.d.(3): Delete subparagraph (d) and insert:

"(d) A disclosure to a State licensing board is to be made by the Director of the health care facility involved. Disclosure to a State licensing board in the absence of a request from the State licensing board will be made only after approval for such disclosure has been obtained by the Director from the Associate Deputy Chief Medical Director and the Medical Inspector (10A6). Consultation with either of these officials may be sought prior to disclosure to a State licensing board, pursuant to an official request from the State licensing board, but is not required."

E. RESCISSION: Interim Issue 00-82-7 and Supplement No. 1 will expire March 31, 1984.

HARRY N. WALTERS
Administrator

Distribution: RPC: 5038
FD

VETERANS ADMINISTRATION
Washington, D.C. 20420

March 12, 1982

INTERIM ISSUE 00-82-7
(Confirming Teletype Transmission)

A. BASIC ADMINISTRATIVE ISSUE AFFECTED: MP-5, Part I, Chapter 297.

B. OTHER ISSUES AFFECTED: None.

C. REASON FOR ISSUE: (1) To provide policy and guidelines regarding the disclosure of information from personnel records on terminated employees upon request of a State licensing board; and (2) to outline procedures and guidelines regarding the disclosure of information on terminated employees to a State licensing board in the absence of a State licensing board request when the termination was based on a significant failure to conform to generally accepted standards of medical professional practice.

D. TEXT OF ISSUE: MP-5, Part I, Chapter 297, is changed as follows:

Page 4, paragraph 9: New subparagraph 9d is added as follows:

d. State Licensing Boards

(1) It is the policy of the VA to cooperate with a State licensing board officially inquiring into the professional performance history of former VA personnel who are under the jurisdiction of that State board. Moreover, under special circumstances, it is also the policy of the VA to notify a State licensing board of jurisdiction that a terminated health care professional has significantly failed to conform to generally accepted standards of medical professional practice. In order to avoid any conflict with these disclosure policies, VA officials are not authorized to enter into any written or oral agreements which would prohibit or restrict the release of information to a State licensing board.

(2) Generally, most of the professional performance history on a terminated VA health care professional employee is contained in the Professional Standards Board Action Folder. This personnel record is considered to be a part of VA Privacy Act system of records entitled "29VA11, Physician, Dentist, and Supervisory Nurse Professional Standards Board Action File-VA" (see MP-1, Part II, Chapter 21, Appendix B.) Other professional performance history on various terminated VA health care professional employees may be included in general personnel records systems such as the Official

Personnel Folder. Thus, notwithstanding the above-stated policies of cooperation with State licensing boards, any disclosures of information from personnel records without the prior written consent of the terminated employee must be consistent with the provisions of the Privacy Act of 1974 and in compliance with any other laws which may statutorily restrict the disclosure of various information.

(3) The following guidance is provided regarding the release of information.

(a) The Privacy Act permits the VA to disclose information from personnel records without the prior written consent of the terminated employee when the head or an official of another agency or instrumentality of any governmental jurisdiction within or under the control of the United States and authorized by law to conduct civil or criminal law enforcement activities makes a written request to the VA for the information in personnel records in the possession of the VA and identifies the law enforcement activity for which the record is sought. 5 U.S.C. 552a(b)(7); 38 C.F.R. 1.576(b)(7). A State licensing board qualifies as such a law enforcement instrumentality within the meaning of 5 U.S.C. 552a(b)(7). Accordingly, upon receipt of a written request for information regarding a terminated VA employee by the head or a supervisory official of a State licensing board which specifies the reasons for which the information is sought, the VA shall, unless otherwise directed by VACO, comply with such requests as expeditiously as possible.

(b) There may be circumstances when the VA has personnel record information concerning a terminated VA health care professional which indicates that the termination was based on a significant failure to conform to generally accepted standards of medical professional practice. The VA may disclose this information to a State licensing board of jurisdiction even without a written request from the board relevant to this failure. Such disclosure is authorized under the Privacy Act by means of a "routine use." A "routine use" publicly identifies in the Federal Register those situations when agency personnel may disclose a record from a record system without the written consent of the individual to whom the record pertains. 5 U.S.C. 552a(b)(3). In the system of records, 29VA11, the system contains two routine uses, numbers 1 and 3, which permit the disclosure of information from the record to: (1) a State licensing board if the records indicate a potential civil or criminal violation of law; or (3) in those instances when the information is relevant to a State licensing board decision concerning the issuance of a license or registration. In the system of records covering general personnel records, OPM/GOVT-1, the system contains two routine uses, k. and l., which permit the disclosure of

information from the Official Personnel Folder to a State licensing board for the same reasons identified above.

(c) Personnel records may contain information concerning the medical treatment of veterans or other personal information relating to a veteran or a dependent. Prior to release of information from personnel records to a State licensing board, the VA must delete any information which is subject to the confidentiality provisions of 38 U.S.C. 3301(f), 4132; and 38 C.F.R. 1.500, et seq. Specifically, identifying information (i.e., name and address) about a veteran or a dependent, and identifying information relating to drug, alcohol, or sickle cell anemia treatment may not be disclosed to a State licensing board absent the specific written consent of the individual to whom the information pertains.

(d) When a VA facility receives a request for information concerning a terminated employee from a State licensing board, the Director of each facility will acknowledge such request, maintain a file on each department or agency involved, and assure compliance with the request as soon as possible.

(e) The Privacy Act Officer at each facility will be responsible for ascertaining that the provisions of the Privacy Act are met and that all VA confidentiality statutes are complied with.

(f) Should the Director or Privacy Act Officer have questions regarding the appropriateness of a disclosure of information to a State licensing board, the District Counsel should be consulted.

E. RESCISSION: This Interim Issue expires March 31, 1983.

Robert P. Nimmo

ROBERT P. NIMMO
Administrator

Distribution: RPC: 5038
FD

39-069 O—84——6

Question 8A.

On page 5 of his testimony, Dr. Clinton described DOD efforts "to specify performance standards which can serve, in part, to identify health care providers delivering less than acceptable care." In my view, development and use of such objective standards are important elements in a quality assurance effort.

Has the VA developed such objective standards and are they in use?

Answer 8A. No.

Question 8B(i). (If so) Please provide copies of any such standards

Answer 8B(i). Not Applicable.

Question 8B(ii). (If no) Please examine the DOD standards and provide your views on whether they should be adopted for use in the VA.

Answer 8B(ii). Our system is structured such that each medical center monitors the care provided by the physicians in that medical center. This monitoring is done through Morbidity and Mortality Conferences, various Service conferences, and other components of the Systematic Internal Review Program. Our structured system of supervision provides for the ability to evaluate performance on a daily basis and provides an opportunity to document problems, initiate counseling, and take remedial action in a timely fashion. The trending done within the facility provides another mechanism to flag possible problems with providers.

The staff at VAMC's are not nearly as transient as DOD, thus the medical centers, in general, know the capability of their staff and, in fact, review it each year during the credentialing process. In addition, various external reviews, such as SERP, JCAH, etc., review performance. We have found that the systems just described function effectively. The system described by DOD is in the process of being implemented. We will watch with interest to see how effective and functional this sytem is.

Question 9A.

I am concerned that in-house VA employees, because they have to look to their future within DM&S, may not always be the best choice to carry out investigations on behalf of the MI.

Do you agree that there is a basis for such concerns?

Answer 9A. Generally, I do not agree with this concern. There are some individuals who, regardless of their good intentions, are not capable of objectively judging the performance of others. These people are not used for investigations. Those used are believed to be able to assess problems

fairly and accurately and to arrive at reasonable conclusions. Reprisals are not a factor since they come from other VAMC's and are not subject to the authority of those in the institution being visited. They are also protected by the authority of the Chief Medical Director. Typically, we utilize professsionals from outside the Medical District involved.

Question 9B. When in-house employees are used for investigations, how can the MI or Chief Medical Director ensure that the investigations are as rigorous as possible?

Answer 9B. Each team member is thoroughly briefed on the issues involved and the areas to be elucidated prior to the visit. They are assured of the full support of the Office of the Chief Medical Director and of the need for an objective appraisal, with emphasis on the welfare of the patient. If, after reporting back, additional clarification is required, this is obtained.

Question 9C. How frequently does the MI utilize outside consultants (such as DOD did when it utilized Dr. Cooper in the Wilford Hall investigation) to carry out investigations?

Answer 9C. The MI has not, to date, utilized outside consultants but stands ready to do so if the circumstances warrant.

Question 9D. One other possible approach to removing any possible concern about the effectiveness of using in-house VA employees would be to enter into agreements with DOD pursuant to which VA employees would carry out investigations for DOD and DOD employees would carry out VA investigations. Please comment on such an arrangement.

Answer 9D. Such an arrangment would be awkward at best. An occasional expert in a specific field might prove of value but as a general rule there are enough differences in mission, structure and procedures within the systems to make assessment of one group by the other group very difficult. DM&S investigators sent by the MI are generally well received within the VAMC's as being supportive and are given total cooperation. Outsiders might be viewed with suspicion and find it difficult to elicit the needed cooperation and information.

RESPONSE OF FRANK S. SATO, INSPECTOR GENERAL OF THE VETERANS' ADMINISTRATION TO WRITTEN QUESTIONS SUBMITTED BY HON. ALAN K. SIMPSON, CHAIRMAN OF THE SENATE COMMITTEE ON VETERANS' AFFAIRS

Question 1.

What resources, including the number and professional expertise of the personnel in your office, are available to aid you in your responsibility for oversight of the Medical Inspector's Office?

Answer 1.

We presently have a full-time senior level investigator and his supervisor who have extensive investigative experience and lay knowledge of medical matters currently responsible for coordinating and overseeing all quality of care medical investigations undertaken by the Medical Inspector. In addition, my entire staff of professional auditors (227) and investigators (66) is available to aid in my responsibility for oversight of the Medical Inspector's Office. I do not presently have any individuals with professional medical expertise on my staff.

Question 2.

You have said that you would use your authority to hire medical experts and consultants if it were necessary to aid you in overseeing the activities of the Medical Inspector's Office, but that up until now you have not seen the need to exercise that authority. Without any medical expertise on your staff, how are you able to evaluate and determine when such expertise is necessary?

Answer 2.

We can only use a common-sense approach when making our evaluations and determinations. Whenever strictly medical questions arise during our reviews, we discuss the matter with the Medical Inspector and his staff. We rely heavily on the expertise and integrity of the Medical Inspector in his responses to our questions. I would not hesitate to use my authority to hire medical experts and consultants if any contradictions were apparent, if there was any reason to doubt the validity of information provided by the Medical Inspector, or if the perception of any lack of independence might jeopardize the case.

Question 3.

In your testimony, you stated that you audit or investigate against certain standards, such as those applied to the operation of renal transplant facilities. As part of your oversight responsibilities pertaining to quality assurance programs, do you apply other performance standards, specifically mortality standards and complication standards, to determine whether medical incidents and physician performances fall within the range of normal clinical behavior or are outside that range? How often is such data applied and reviewed by your office?

Answer 3.

In connection with our audits of medical centers, we routinely review the minutes of professional committee meetings. These files indicate when performance deviates from established norms in such areas as infection control, mortality, drug and antibiotic usage, etc. When, in our opinion, a trend of deviations from norm is observed in any area, we will initiate an audit to determine the cause and to bring the condition to appropriate program management attention for corrective action. In investigatory matters, we rely on the Medical Inspector's Office to determine whether specific medical incidents and physician performance fall within acceptable ranges.

RESPONSE OF FRANK S. SATO, INSPECTOR GENERAL OF THE VETERANS' ADMINISTRATION, TO WRITTEN QUESTIONS SUBMITTED BY HON. ALAN CRANSTON, RANKING MINORITY MEMBER OF THE SENATE COMMITTEE ON VETERANS' AFFAIRS

Question 1A.

When a problem is brought to your attention as Inspector General (IG) that involves quality of care issues as well as issues under the purview of the IG, what steps are taken to coordinate the Medical Inspector's (MI) investigation with that carried out by the IG?

Answer 1A.

Whenever a problem is brought to my attention that involves both quality of care issues as well as issues that fall under my purview, the following steps are taken:

a. The information is reviewed and analyzed to segregate the issues that are strictly quality of care matters from the Inspector General issues.

b. A preliminary meeting is held between the Medical Inspector and members of my investigative staff to discuss the investigation and to determine such matters as who is responsible for investigating which issues; the extent, scope and methodology of the investigation; allocation of resources; investigative timetable; and reporting requirements.

c. Coordination at the investigative site is maintained through meetings between Medical Inspector and Inspector General Investigators.

d. When the investigation is completed, the Medical Inspector's report is reviewed to ensure that all pertinent issues have been covered, that the findings are consistent with the information developed and that appropriate recommendations have been made and acted upon.

Question 1B.

Within the last three years, how many such coordinated or joint IG/MI investigations have been carried out?

Answer 1B.

There have been 8 joint IG/MI investigations carried out in the past three years.

Question 2A.

In the most recent Semiannual Report of the IG, dated April 24, 1984, it was stated that "OIG coordinates reviews and oversees medical investigations conducted by the DM&S Medical Inspector and DM&S field stations."

Exactly what actions are undertaken to carry out this coordination and oversight?

Answer 2A.

The following actions are undertaken to carry out coordination and oversight of medical investigations conducted by the Medical Inspector and DM&S field stations:

a. All documents pertaining to Medical Inspector inquiries and investigations are reviewed. These documents include:

   - Documents that initiate a case, such as an incident report, letter, Hotline report, or report of contact;

   - The Medical Inspector's initial and subsequent requests for information sent to Field Stations or elements within Central Office;

   - All reports and responses from Field Stations and elements within Central Office;

   - The Medical Inspector's report and recommendations;

   - The closing documents, to include statements of actions taken as a result of Medical Inspector recommendations; and

   - Copies of all complaints, incident reports and station investigative reports that do not result in investigative action by the Medical Inspector.

b. All quality of care investigations are reviewed for completeness, adequacy of process and reasonableness of actions taken.

c. Suggestions to improve the quality of field station investigations are provided to the Medical Inspector as needs are identified.

d. Technical investigative assistance is provided to the Medical Inspector when appropriate.

e. Recommendations are made to the Chief Medical Director regarding system wide trends or problems observed as a result of our oversight activities.

f. Close and continuous liaison is maintained with the Medical Inspector's office, with representatives of the OIG and the Medical Inspector routinely discussing on-going reviews and investigations. These meetings are regularly scheduled and documented.

g. Relevant investigative training is provided to Department of Medicine and Surgery field station personnel as resources allow.

h. All joint investigative endeavors are closely coordinated. (see response to question 1A).

i Special reviews of Medical Inspector activities are conducted when deemed necessary.

Question 2B.

What office or specific employees in OIG carry out this activity?

Answer 2B.

I have established a Medical Inspector Oversight Office within the Special Operations Division of the Office of Investigations. We presently have a full-time senior level investigator and his supervisor who have extensive investigative experience and lay knowledge of medical matters currently responsible for coordinating and overseeing all quality of care medical investigations undertaken by the Medical Inspector. In addition, my entire staff of professional auditors and investigators is available to aid, as requested, in my responsibility for oversight of the Medical Inspector's Office.

Question 2C.

As a result of this coordination and oversight, does OIG ever direct MI to modify the conduct of ongoing investigations?

Answer 2C.

To date we have not found it necessary to direct the Medical Inspector to modify the conduct of an ongoing investigation. I would not hesitate to do so if the need ever arose.

Question 2D.

(If yes) Please provide examples of cases in the past year in which this has occurred.

Answer 2D.

Not applicable

Question 3A.

During a June 11, 1980, Committee oversight hearing on activities of the VA's IG, at which the establishment of the MI was discussed, your predecessor, Allan Reynolds, indicated his intention to maintain rigorous oversight of the effectiveness and independence of the MI.

Have you maintained a commitment to such oversight?

Answer 3A.

I remain committed in maintaining rigorous oversight.

Question 3B.

In what ways do you monitor the effectiveness of the activities of the MI? In asking this question, I am not focusing on your evaluation of the substance of particular medical judgments made by the MI or field investigators but rather an evaluation of the effectiveness of the operation of the MI. In this regard, please indicate how you evaluate--

(i) the way in which complaints are processed by the MI;

(ii) the way in which the MI picks locations for site visits;

(iii) how field investigators are selected and prepared to carry out investigations;

(iv) how investigations are actually carried out;

(v) how results of investigations are presented to appropriate DM&S officials; and

(vi) how the MI follows up on investigation reports and recommendations for action.

Answer 3B.

The primary method used to monitor and evaluate the effectiveness of the Medical Inspector's activities in all six areas listed in your question is through critical review of all Medical Inspector and field station investigative reports and through frequent visits to the Medical Inspector's office during which the Medical Inspector's operations are observed and discussed. In addition, a special review of the Medical Inspector's office, conducted at my direction by my staff in October 1982, showed that the Medical Inspector's office was generally effective in carrying out its responsibilities for managing and accomplishing quality of care investigations. Some

improvements were needed in such areas as documentation, coordination and communication between the OIG and the Medical Inspector, and in the accuracy of tracking Medical Inspector cases. These improvements have been made. Similar reviews will be conducted in the future when a need is indicated.

Question 4.

In cases referred to the MI from sources other than the IG, how do you ratify determinations made by the MI that the allegations involve quality of care issues and are therefore not under your jurisdiction?

Answer 4.

Information regarding cases referred to the Medical Inspector from sources other than the Inspector General is furnished to the Medical Inspector Oversight Office. This information is reviewed to ensure that the allegations involve only quality of care issues and that matters falling under IG jurisdiction are referred to the appropriate IG office. Reports of all cases investigated by the Medical Inspector are also carefully reviewed to ensure that only quality of care matters are investigated. We have noted no instances whereby the Medical Inspector has exceeded his jurisdiction and we are satisfied that he is reporting matters falling under IG jurisdiction to us.

Question 5.

In a case brought to the IG which involves an allegation of misfeasance or malfeasance on the part of a professional in VA other than a physician (e.g., an attorney in a District Counsel's office), do you seek the assistance of a member of the profession in question to carry out an investigation?

Answer 5.

We do seek the assistance as required of members of the profession in question in carrying out an investigation if matters arise that involve professional performance in areas beyond the qualification of the investigator or other members of my staff.

Question 6A.

With reference to the members of your office who carry out investigations --

What qualifications do you look for in selecting a person for such a job?

Answer 6A.

We look for individuals with general and specialized criminal investigative experience in which they demonstrated initiative, ingenuity and resourcefulness, and the ability to collect, assemble and develop facts and other pertinent data. The individual must have the ability to think logically and objectively, to analyze and evaluate facts, evidence and related information, and to arrive at sound conclusions. Skill in oral and written communications is required and the individual must have tact, discretion and the capacity for obtaining the cooperation and confidence of others.

Question 6B.

What training is provided to your investigators, either at the time they are first employed or on an ongoing basis, to enhance their ability to carry out investigations?

Answer 6B.

All of our investigators are required to have basic criminal investigative training equivalent to the seven-week Criminal Investigator Training Course presented at the Federal Law Enforcement Training Center at Glynco, Georgia. New employees who have not had such training are sent to the training center at Glynco shortly after they are first employed. We also provide continuous in-house training in the various investigative disciplines and our investigators are required to periodically attend various advanced investigative training courses and seminars presented by the Department of Justice and other investigative agencies and associations.

Question 6C.

What role does your office play in providing training to employees who carry out investigations for the MI.

Answer 6C.

We have developed a training package to be used by other investigative personnel responsible for conducting MI facility level investigations. This training is provided to personnel either at a specific facility or to personnel from several facilities through programs presented at a Regional Medical Education Center. We have noted a marked improvement in the completeness of investigations conducted by medical facility personnel since this program was initiated two years ago.

Question 7.

When you receive allegations of wrongdoing at a particular VA station, what role does the station director play in investigating or resolving the complaint?

Answer 7.

If we receive an allegation of wrongdoing at a particular VA station that requires investigation by my office, the station director's role is limited to that of a contact point for the IG investigator and, if appropriate, as the individual responsible for taking actions as a result of investigative findings. If the allegations do not require an investigation by my office, the matter is referred to the Medical Inspector who, depending upon the nature of the allegations, either initiates an investigation out of his office or sends the allegation to the station director through the appropriate regional director for investigation or resolution of the complaint. The station director is responsible for sending a report regarding his investigation or other actions to the Medical Inspector.

Question 8A(i).

On page 3 of the agency's testimony, it is stated that "(a)ll cases generated by the Medical Inspector are reported to the Inspector General and copies of all VA Medical Center investigations are routed to them"

When your office receives reports on MI-conducted investigations, what action is taken to evaluate the results and recommend any appropriate changes in the report?

Answer 8A(i).

When my office receives reports on Medical Inspector conducted investigations, the reports are critically reviewed by the Medical Inspector Oversight Unit to determine completeness, adequacy of process and reasonableness of actions taken. If any deficiencies are noted, the report is returned to the Medical Inspector with our findings and we maintain the case in a pending status until a final report is provided by the Medical Inspector.

Question 8A(ii).

How does your office monitor quality and consistency of MI investigations?

Answer 8A(ii).

The quality and consistency of Medical Inspector investigations are monitored through the critical review process of all Medical Inspector investigative reports. The reviewer carefully reads the entire report and all attached documents to determine if all allegations were fully covered, if all necessary interviews were conducted and if all necessary leads were pursued. He also determines if the investigatory conclusions are fully supported by the evidence developed and if reasonable actions were taken as a result of the findings. The report is also reviewed to determine if the findings and actions could have system-wide applications, and if so, that appropriate actions were taken by DM&S to correct systemic problems.

Question 8B(i).

In this regard, please review and comment on the IG's role with reference to the MI's investigation over the past two years of certain allegations concerning matters in the Laboratory Service at the Sepulveda VAMC.

Specifically, please review and compare two MI reports on this investigation -- one included in a February 25, 1982, letter to the MI from a field physician who carried out a special purpose visit on behalf of the MI, and the other enclosed in a February 10, 1984, letter to me from the MI -- and provide your views on the MI's efforts on this investigation in light of the differences between these two reports.

Answer 8B(i).

The first investigation was conducted by Dr. Tatsuo Sato in February 1982 as a result of a letter from the Office of the Special Counsel to the Administrator of Veterans Affairs. The investigation was concentrated in two areas: (1) propriety of frozen section performance and (2) quality of the Laboratory Service performance in general and the leadership quality of the Chief, Laboratory Service. Regarding the first allegation, the examination of the laboratory log book relating to specific cases alleged to be examples of delays in the processing of frozen sections showed that no undue delays had occurred. The Chief of Surgery and the Head Operating Room Nurse supported this finding by stating that there were no significant problems relating to frozen sections.

The review of the quality of laboratory service performance and the leadership quality of the Chief of Laboratory Service showed that the Laboratory Service's productivity was average to the VA; that their budget was very reasonable and not out of line; and that there were no significant equipment problems. However, problems were found in the amount of laboratory space available, organizational and staffing alignments and in policy regarding satellite laboratories. Appropriate corrective recommendations were made. In addition, a review of surgical pathology and autopsy reports revealed no significant problems; however, delays were noted in clerical and transcription support which resulted in a significant backlog of reports. It was recommended that the Chief of Laboratory Services address these problems to avoid unnecessary delays in reporting.

In addition, it was reported that the Chief of Laboratory Service was a professionally accomplished pathologist who was preoccupied with professional work and who delegated most administrative details to his staff. Dr. Sato reported that he could not accurately evaluate the Chief's managerial skills during his brief observation but he did report that the Chief was apparently not well versed in the Automated Management Information System, budget or space figures.

The other investigation relating to laboratory operations at Sepulveda was conducted by the Medical Inspector in October 1983 based upon allegations from a laboratory employee. The allegations covered included the non-availability of pathologists to conduct timely frozen section examinations and delays in conducting autopsies. Also, allegations such as time and attendance irregularities and outside professional activities being conducted by one of the pathologists were investigated by the OIG's office in coordination with the Medical Inspector's investigation.

The Medical Inspector found that on some occasions the pathologists were not available when frozen sections were ready to be examined but that the Chief of Surgery was not too concerned because the problem was infrequent and because the problem cleared up after he talked to the pathologists. The Medical Inspector also determined that there was a resistance on the part of the pathologists to conduct autopsies and that one of the pathologists had attempted to postpone over a weekend an autopsy that was required to be done on a Friday. The Medical Inspector found no evidence that the pathologists' clinical work was unacceptable but that their attitude and work habits were.

The investigation was then expanded to focus on the administrative abilities of the Chief of Laboratory Services. It was found that although the Chief was a very competent pathologist, he was a poor administrator who did not like to make decisions and who did not exercise adequate supervision. A recommendation was made to remove and replace the Chief of Laboratory Service and the Administrative Officer, who has a cardiac disability and was functioning at only one-half of his capacity.

It appears that the main differences in the two reports are primarily differences in the investigative focus and the emphasis placed on the findings. In the first investigation, Dr. Sato focused on the specific frozen section cases reported in the allegations and on the overall clinical operations of the Laboratory Service. In the second investigation, the Medical Inspector, on the other hand, focused on the administrative abilities of the Service Chief and the attitude and performance of the pathologists.

Both investigations found problems in their areas of focus and both made appropriate recommendations to correct the problems they found. It is apparent that the Medical Inspector found the problems to be more serious than the field medical investigator and that the Medical Inspector made more aggressive recommendations. The Medical Inspector did, however, have the advantage of reviewing the prior investigative report, and his recommendations could have been influenced on the fact that the problems uncovered previously had not been corrected by the Service Chief.

Question 8B(ii).

Does this review suggest anything to you about the efficacy of using ad hoc DM&S career employees to do OIG investigations?

Answer 8B(ii).

The example cited above does not support that DM&S employees conducted an OIG investigation and we have never permitted DM&S employees to do so. The only aspect of the Sepulveda investigation that required OIG investigation involved the allegations regarding outside activities of one of the pathologists. These allegations were investigated by an OIG investigator with neither the Medical Inspector nor the DM&S investigator making an attempt to investigate this matter.

Question 8C.

One possible approach to removing any possible concern about the effectiveness of using in-house VA employees would be to enter into agreements with DOD pursuant to which VA employees would carry out investigations for DOD and DOD employees would carry out VA investigations. Please comment on such an arrangement.

Answer 8C.

I agree that the approach you suggest could alleviate some of the concerns regarding the independence and objectivity of quality of care investigations. If the objective is to have non-VA doctors conduct the investigations, DOD may be a good choice; however, consideration should be given to the fact that the Department of Health and Human Services has medical professionals who could accomplish the same objectives. I do not feel that such an arrangement should be made mandatory or used as a matter of routine but rather should be limited to exceptional circumstances such as extremely sensitive cases in which questions of independence could become an issue. I believe that routine cases can be more effectively investigated by in-house VA personnel because of the extensive expertise available in the VA system and the institutional knowledge of the VA personnel. Lack of such knowledge could create some problems to outside personnel.

Question 8D(i).

How frequently does the MI utilize outside consultants (such as DOD did when it utilized Dr. Cooper in the Wilford Hall investigation) to carry out investigations?

Answer 8D(i).

The Medical Inspector has not as yet had occasion to utilize outside consultants to carry out investigations.

Question 8D(ii).

Are you satisfied that this constitutes an appropriate reliance on such outside consultants?

Answer 8D(ii).

In view of the above response no comment is applicable.

Question 8E.

On page 4 of his testimony, Dr. Clinton of the Office of the Assistant Secretary of Defense (Health Affairs), noted that, in the near future, all DOD medical care facilities "will have at least one full-time person to assume the day-to-day responsibilities of coordinating quality assurance activities undertaken by the many staff persons of the facility." If this is a good idea for the much smaller Department of Defense hospitals, would it not be a good idea for each VA health-care facility?

Answer 8E.

I have been informed by the Medical Inspector that the VA already has personnel at VA medical facilities dedicated to quality assurance matters. The activities of the quality

assurance personnel are monitored by the Joint Commission on the Accreditation of Hospitals and each facility is required to meet current JCAH quality Assurance standards.

Question 9A.

What is the IG's role with reference to malpractice claims involving VA personnel?

Answer 9A.

My office would have no involvement in malpractice claims cases unless specific allegations involving mismanagement, fraud or other criminal misconduct were brought to our attention. Responsibilities regarding other malpractice claims cases properly fall under the jurisdiction of DM&S and the Office of General Counsel.

Question 9B.

Specifically, does the IG review malpractice claims in order to evaluate proposed action in such claims, including proposed corrective actions, and, in those cases in which malpractice is found or a settlement entered into, any proposed disciplinary actions?

Answer 9B.

We have not performed reviews or evaluations of malpractice claims to date; however, this area has been planned for review.

Question 9C.

Please provide examples and supporting documentation regarding cases in which you have carried out evaluations in each such instance, including a description of the recommendations you made and the agency's actions regarding them.

Answer 9C.

In view of the above response, I cannot provide the requested examples.

Chairman SIMPSON. We have now panel 2, which consists of Jarrett Clinton, M.D., Acting Deputy Assistant Secretary of Defense for Professional Affairs and Quality Assurance, Department of Defense, Washington, DC; and Alvin Tucker, Deputy Assistant Inspector General for Auditing, Office of the Inspector General, Department of Defense, Washington, DC.

It's nice to have you here this morning. Please go right ahead.

TESTIMONY OF A PANEL OF REPRESENTATIVES OF THE DEPARTMENT OF DEFENSE, CONSISTING OF: J. JARRETT CLINTON, M.D., ACTING DEPUTY ASSISTANT SECRETARY OF DEFENSE FOR PROFESSIONAL AFFAIRS AND QUALITY ASSURANCE, DEPARTMENT OF DEFENSE, WASHINGTON, DC; AND ALVIN TUCKER, DEPUTY ASSISTANT INSPECTOR GENERAL FOR AUDITING, OFFICE OF INSPECTOR GENERAL, DEPARTMENT OF DEFENSE, WASHINGTON, DC

Dr. CLINTON. It's a pleasure to be here this morning to describe for this committee the evolving program in quality assurance undertaken by the Department of Defense.

I have submitted written testimony for this committee.

I would like to emphasize in these few brief moments, the evolutionary nature of our program. It began in an appropriate response to specific events that occurred about 2 years ago, but now has become, I think, a much more broadly based program to encompass a whole range of quality assurance issues that can help us provide the best possible care we can.

Briefly, we have stimulated the organizational priorities of quality assurance within the Department at the highest level of command and at the hospital level.

We have improved the reporting to our civilian colleagues of instances where providers have been relieved of clinical privileges within our system or when their privileges have been restricted.

We have improved our responsiveness to instances of substandard care or unethical behavior on the part of health-care providers.

We have established performance criteria for assessing and measuring the quality of care provided by our health-care providers. We have established standards for nonphysician health-care providers such as nurse midwives, nurse anesthetists, and physician assistants.

Those standards include educational standards, standards of supervision, and standards relating to the practice of their particular activities.

We are in the process, in the final coordination phase, of establishing standards on credentialing and licensing for the range of health-care providers in our system.

We are exploring a number of means now using automated data processing techniques to find easier and better ways to monitor medical records, hospital discharge data or other data bases so that we can establish an on-going surveillance system to ensure that the policies that we have enunciated previously and the issues that may come up in the future can be dealt with as quickly as possible.

All these things, we believe, will sustain the quality of care, improve it, improve our capacity to respond appropriately, and im-

prove the very structure of medical care within the Department of Defense.

I'd be happy to respond to your questions.

Chairman SIMPSON. That was delightfully precise. I want to thank you for that. It seldom happens that way here.

[The prepared statement of J. Jarrett Clinton, M.D., Acting Deputy Assistant Secretary of Defense for Professional Affairs and Quality Assurance, Department of Defense, Washington, DC, follows:]

PREPARED STATEMENT OF J. JARRETT CLINTON, M.D., ACTING DEPUTY ASSISTANT SECRETARY OF DEFENSE FOR PROFESSIONAL AFFAIRS AND QUALITY ASSURANCE, DEPARTMENT OF DEFENSE, WASHINGTON, DC

Mr. Chairman, members of the Committee. I am Jarrett Clinton, M.D. It is a pleasure for me to have this opportunity to represent William Mayer, M.D., the Assistant Secretary of Defense for Health Affairs, in describing to the Committee on Veterans Affairs the quality assurance program within the Department of Defense (DoD).

Background

About two years ago the CBS "60 Minutes" television program aired the Stanford case, involving medical malpractice by an Air Force surgeon. The adverse publicity and specter of inadequate quality within the military health care system stimulated by this case prompted DoD to initiate a series of detailed audits and reviews of the medical care system to determine the extent of potential problems.

A sufficient number of system-wide deficiencies were found within DoD's medical care programs. Thus, the Assistant Secretary of Defense for Health Affairs initiated an intensive effort to strengthen the quality of medical care standards and monitoring throughout the military health care system. An Office of Quality Assurance was established under the Assistant Secretary for Health Affairs to provide the necessary leadership for this effort.

The Quality Assurance Office is charged with developing and maintaining a strong and assertive quality assurance program for DoD. It has a three-part function consisting of quality assurance policy making, policy implementation, and policy enforcement. Health Affairs' Quality Assurance Office assumes major responsibility for quality assurance policy making and implementation. We rely on the DoD Inspector General for independent audits and inspections to ensure that quality assurance policies are followed throughout the military health care system.

One of the first tasks of the Health Affairs Quality Assurance Office was to undertake a comprehensive review and evaluation of existing efforts devoted to medical care quality assurance within the Military Departments. This review examined the organizational levels within each Department at which quality assurance activities occurred and the adequacy of quality assurance programs in meeting Joint Commission on Accreditation of Hospitals guidelines. This review plus medical program audits and an analysis of malpractice claims experience within DoD highlighted specific deficiencies in the quality of care being provided within military medical treatment facilities. The major areas of weakness that were found included the lack of standards by which to measure health care providers' clinical performance, inadequate supervision of nonphysician health care providers, failure to establish and adhere to adequate credentialing

procedures for applicable health care providers, misconduct of health care providers adversely affecting patient care, and incompetence and impairment among health care providers resulting in medical mismanagement.

Current Organization and Staffing

Dr. Mayer has on numerous occasions expressed his commitment to enhance the high quality of medical care within each facility. To strengthen our capacities within Health Affairs, quality assurance activities are now included within the responsibilities of the Deputy Assistant Secretary of Defense for Professional Affairs and Quality Assurance. Our medical care quality assurance activities are undertaken currently by a health services administrator and a clinical nurse, both under my direct supervision.

Following the formation of the Office of Quality Assurance within Health Affairs was the establishment of a Tri-Service Committee on Quality Assurance to review, assess and propose quality assurance policy. Service representation on the Tri-Service Committee consists of each Service's Director of Quality Assurance, the head of the established office of quality assurance at the Surgeon General level. Each Service's Office of Quality Assurance has from two to four professional staff led by a physician to focus exclusively on medical care quality assurance issues.

At the command levels of each Service, staff are being identified to provide greater cohesiveness to the many quality assurance efforts now underway in each medical treatment facility.

Within medical care treatment facilities quality assurance staff have been appointed or are in the process of being appointed. Our large teaching centers have from 6-10 professionals assigned to these quality assurance efforts. In smaller facilities a lesser number of staff are needed for activities. Within the near future we expect that each medical care facility, even those providing solely outpatient services, will have at least one full time person to assume the day-to-day responsibilities of coordinating quality assurance activities undertaken by the many staff persons of the facility.

Policy Actions

I now turn to a specific listing of quality assurance policy decisions issued since FY 82. Our first action was to establish a system whereby the Services report information on malpractice claims and adverse credentials actions of health care providers. The malpractice claims data are received and reviewed primarily by the Services and Armed Forces Institute of Pathology.

To respond rapidly to the issue raised in the Stanford case of inadequate providers moving from the Services to civilian positions, we issued in July 1982 DoD Directive 6000.7, (Enclosure A), "Dissemination of Information on Medical

Officers". This directive requires each Military Department to report to the Federation of State Medical Boards those medical officers whose clinical practice privileges are suspended, limited or withdrawn at the time they are separated from the Service. In addition, if a medical officer seeks training at a civilian institution, the training institution will also be notified of such credentials actions.

We then moved to specify performance standards which can serve, in part, to identify health care providers delivering less than acceptable care. Issuance in April 1983 of DoD Directive 6025.1, (Enclosure B), "Standards for DoD Health Care Provider Performance," requires the establishment and review of performance standards for DoD health care providers based on mortality and complication rates for medical and dental procedures and treatments. These performance standards are also reviewed at the time of clinical privileges renewal. We have received the mortality data from the last half of CY 1983 and expect to receive complications data from the Services for a substantial part of CY 1984. These data provide an excellent means to monitor provider performance, assess trends and assure that appropriate actions are taken when any of the rates for a particular provider or institution is outside predetermined parameters.

We subsequently turned to issues surrounding nonphysician health care providers. DoD Directive 6025.2, "DoD Nonphysician Health Care Providers," issued in November 1983, (Enclosure C), increases the amount and quality of physician supervision exercised over DoD nonphysician health care providers, such as physician assistants and nurse practitioners. It establishes minimum requirements for nonphysician providers in the areas of supervision and review, duties and responsibilities, and education and training.

Policy Actions in Process

In addition to these accomplishments, five proposed policy actions are underway. The first of these will establish strong and effective measures to ensure that prompt actions are taken to identify and remove from patient care responsibilities those credentialed providers engaged in unprofessional, unethical activities or substandard medical or dental practice. A July 1983 memorandum sent by the Secretary of Defense to the Service Secretaries stresses the importance of timeliness of actions in cases of suspected health care provider misconduct in medical care activities or substandard medical practice. The memorandum gave specific guidelines to be followed in such cases pending issuance of an appropriate directive. A DoD Directive to replace the Secretary of Defense guidance is in the final coordination process and will be issued this summer.

Secondly, we expect to tighten the Military Departments' existing credentials guidelines and requirements to ensure that providers given authority to initiate or alter regimens of medical or dental care are credentialed for those specific clinical privileges. Correction of deficiencies in the credentialing programs of the Military Department was designated by the Defense Health Council as a priority quality assurance issue in 1983. A Tri-Service working group was chartered to study the problem. In September 1983 this group reported the Services' credentialing programs with recommendations for changes. A draft of a proposed DoD Directive implementing these recommendations is currently in the coordination process and will be issued this summer.

To explore the most efficient, effective means to monitor quality assurance, we are developing under contract a methodology for assessing the quality of care being provided by our military medical treatment facilities. Health Data Institute, Inc., (HDI) a Boston area health care research firm, has been contracted to identify optimal measures, criteria and standards that could be used by the Military Services to assess, on a continuing basis, the quality of care provided within military health care facilities. The first phase of HDI's efforts uses existing, computerized patient discharge data from each of the Services to screen for gross quality of care problems in terms of morbidity and mortality associated with common diagnoses and procedures, plus an analysis of adverse occurrences which may be indicative of poor quality care.

The problems of appropriate staffing and utilization of emergency departments within health care facilities, military as well as civilian, are problems of long standing. The health care industry continues to experience problems in the emergency room setting that relate to improper staffing or utilization and that result in patient morbidity or mortality and subsequent liability actions. We believe that DoD may be able to make a significant contribution to the health care community at large by hosting a conference that can initiate discussions leading to some pragmatic solutions to these common problems. This conference is planned for November 1984 in Washington, DC.

Finally on our list of actions planned for the near future, we are developing a quality assurance data base module for Health Affairs as part of the Defense Medical Information System (DMIS). The design of this computerized system will allow computer storage of and access to all data reported by the Services in accordance with various quality assurance reports and DoD Directives. Further, it allow direct computer access to the respective Service's biostatistical automated systems for comparative analyses and other quality assurance reviews.

Future Plans

We believe that the past and current actions establish a firm foundation for a DoD quality assurance program. We expect to continue our exploration of means to enhance quality assurance

efforts within the Department of Defense. In concert with the DoD Inspector General we will monitor closely the various quality assurance regulations and guidance provided by the Services to their treatment facilities. Further, we intend to support the need for appropriate minimum levels of staffing for quality assurance activities at all organizational levels within the military health care system and nurture the establishment of microcomputer quality assurance data system capability throughout our medical care program.

We believe that the Department of Defense has an outstanding medical system. As the system grows and as medical care becomes more complex, it does become necessary to institute monitoring and surveillance systems to replace the unspecified trust of yesteryears. We believe that quality assurance programs do enhance patient care and in the long run should contribute to medical care cost containment.

Thank you for this opportunity to describe our medical care quality assurance program.

July 29, 1982
NUMBER 6000.7

ASD(HA)

Department of Defense Directive

SUBJECT: Dissemination of Information on Medical Officers

References: (a) Deputy Secretary of Defense Memorandum, "Dissemination of Adverse Information on Medical Officers," March 16, 1982 (hereby canceled)
(b) DoD Directive 5400.11, "Department of Defense Privacy Program," June 9, 1982

A. PURPOSE

Under reference (a), this Directive establishes policy, provides guidance and assigns responsibilities regarding dissemination of information concerning limitations imposed on DoD medical officers by official action.

B. APPLICABILITY

This Directive applies to the Office of the Secretary of Defense and the Military Departments (hereafter "DoD Components").

C. DEFINITION

1. Medical officer. A military or civilian doctor of medicine or osteopathy, serving in or employed by the Department of Defense.

2. Clinical practice privileges. The inpatient and ambulatory clinical activities permitted a medical officer, upon recommendation of a credentials review board and approval of the medical officer's commander, in accordance with applicable regulations of the Military Department concerned.

D. POLICY

It is the policy of the Department of Defense that when a medical officer is in any way unfit to execute his or her responsibilities in the practice of medicine or osteopathy that the medical officer's commander or supervisor will initiate immediately appropriate action, under the credentials review process of the Military Department concerned, to suspend, limit, or withdraw the medical officer's clinical practice privileges. This is not only a regulatory requirement, but a moral and ethical responsibility of the officials involved.

E. PROCEDURES

1. Completion of credentials review process. A medical officer may not be separated or terminated at the discretion of the DoD Component

concerned while the subject of a credentials review process, except that separation or termination may be authorized in unusually compelling cases by the Secretary of the Military Department concerned.

2. Medical officers on active duty or currently employed. In any case whereby a medical officer's clinical practice privileges are suspended, limited, or withdrawn, a command review shall be conducted to determine whether the officer should be considered for separation or termination. If the medical officer whose privileges are suspended, limited, or withdrawn is not separated or terminated, and he or she seeks training at a civilian institution or organization, such institution or organization shall be notified of the actions in question. When a medical officer is ordered to practice or receive training in a military or civilian facility other than that at which his or her credentials file is maintained, the gaining facility shall be informed fully of the officer's qualifications, including disclosure of suspension, limitation, or withdrawal of clinical practice privileges.

3. Medical officers who are separated. Appropriate professional regulating authorities shall be notified of the identity of medical officers who are separated, whose employment is terminated, or who retire while their clinical practice privileges are suspended, limited, or withdrawn. This requirement does not apply when the suspension, limitation, or withdrawal is for administrative reasons (such as inadequate equipment and lack of qualified support personnel).

F. RESPONSIBILITIES

1. The Assistant Secretary of Defense (Health Affairs) shall monitor the implementation of this Directive.

2. The Secretaries of the Military Departments, or their designees, shall:

a. Administer the policy prescribed herein for medical officers under their jurisdiction, consistent with the provisions of DoD Directive 5400.11 (reference (b)) and arrange for the publication of routine use notices covering the release of information under this Directive.

b. Disseminate appropriate information developed as authorized under section E., above, in accordance with section G., below.

c. Ensure that all information transmitted in accordance with section G., below, has been developed in proceedings that accorded due process to the medical officer whose performance or competence is at issue.

G. INFORMATION REQUIREMENTS

1. The method of reporting information will be through the Federation of State Medical Boards, using the format attached as enclosure 1.

2. Report Control Symbol DD-HA(AR) 1602 has been assigned to this information requirement.

H. EFFECTIVE DATE AND IMPLEMENTATION

This Directive is effective immediately. Forward one copy of implementing documents to the Assistant Secretary of Defense (Health Affairs) within 120 days.

Frank C. Carlucci
Deputy Secretary of Defense

Enclosure - 1
Reporting format

39-069 O—84——8

Jul 29, 82
6000.7 (Encl 1)

Report Control Symbol DD-HA(AR)'02

REPORTING FORMAT

Executive Director - Secretary
Federation of State Medical Boards
of the United States, Inc.
1612 Summit Avenue, Suite 308
Fort Worth, TX 76102

Dear Sir:

Under the agreement between your organization and the Department of Defense concerning the reporting of physicians separated from the Department of Defense under circumstances in which limitations have been imposed on their clinical practice privileges, the following information is submitted.

Physician affected:

Full name (last, first, middle initial) _____
Degree _____
Graduated from _____
Home of record at time of separation from the Department of Defense _____
_____
_____
Date of birth: _____
Licensed in State of: _____
Date licensed: _____
Type of action: _____
_____
Date of action: _____
Summary of facts: _____
_____
_____
_____
Official from whom additional information may be obtained: _____
_____
_____
_____
Phone number: _____

Sincerely,

April 19, 1983
NUMBER 6025.1

Department of Defense Directive

ASD(HA)

SUBJECT: Standards for DoD Health Care Provider Performance

References: (a) Secretary of Defense Memorandum, "Standards for Health Care Provider Performance," March 1, 1983 (hereby canceled)
(b) "International Classification of Diseases, 9th Revision, Clinical Modification," Volume 3, 2nd Edition, September 1980[1]
(c) DoD Directive 5400.11, "Department of Defense Privacy Program," June 9, 1982

A. PURPOSE

This Directive:

1. Establishes policy, prescribes procedures, and assigns responsibilities for evaluating performance by DoD health care providers within military medical treatment facilities (MTFs) and dental treatment facilities (DTFs).

2. Cancels reference (a).

B. APPLICABILITY AND SCOPE

1. This Directive applies to the Office of the Secretary of Defense and the Military Departments.

2. Its provisions cover DoD military and civilian health care providers in military MTFs and DTFs.

C. DEFINITIONS

1. Complication. Any event, whether iatrogenic or spontaneous, either of omission or commission, that represents a significant deviation from the expected process or outcome of a particular medical or dental treatment.

2. DoD Health Care Providers. Military or civilian health care personnel who, under regulations of the Military Department concerned, are credentialled to provide medical or dental treatment in military MTFs and DTFs.

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[1] Available from the U.S. Department of Health and Human Services, Public Health Service - Health Care Financing Administration, 200 Independence Avenue, S.W., Washington, D.C. 20201.

3. Procedure. An operation, obstetrical procedure, or diagnostic and therapeutic procedure listed in the "International Classification of Diseases, 9th Revision, Clinical Modification" (reference (b)).

4. Treatment. The management and care of a patient for the purpose of combating disease or disorder.

D. POLICY

It is the policy of the Department of Defense to ensure that quality care is provided to DoD beneficiaries within military MTFs and DTFs. Thus, it is essential that standards for DoD health care providers' performance be established and incorporated within the Military Departments' quality assurance programs.

E. PROCEDURES

1. Each Military Department shall prescribe complication and mortality rate norms to be used as standards against which DoD health care provider performance shall be measured. Norms are required to be prescribed only for treatments and procedures involving a complication, a death, or both. The standards established for each Military Department shall be applied to MTFs and DTFs throughout that Department. These DoD health care provider performance standards shall be based on norms prescribed for the following:

a. Mortality rates.

b. Complication rates.

2. Prescribed complication and mortality rate norms may be revised as necessary but no more frequently than once each calendar year.

3. Each MTF and DTF shall review all deaths and cases involving complications within the MTF and DTF. DoD health care providers identified in the review as being associated with a complication, a mortality, or both, shall have their complication or mortality rates, or both, computed for the treatment or procedure involved each calendar year. Each MTF and DTF shall compare these providers' rates to the norms prescribed under subsection E.1., above. DoD health care providers whose rates do not fall within the norms shall be identified, reasons for not meeting the norms shall be determined and evaluated, and needed corrective action shall be taken.

4. A copy of each DoD health care provider's most recent complication and mortality rates shall be provided to the Credentials Committee for its review at the time it conducts the annual assessment of the provider's clinical privileges and whenever deemed appropriate by the Credentials Committee. Each DoD health care provider's rates shall become a permanent part of his or her credentials file, which shall be maintained in a system of records established in accordance with DoD Directive 5400.11 (reference (c)).

5. Each MTF and DTF commander shall certify annually to the next higher level in the medical chain of command that each DoD health care provider's complication and mortality rates have been reviewed and evaluated and that necessary corrective actions have been taken, in accordance with the requirements in subsection E.3., above.

April 19, 83
6025.1

F. RESPONSIBILITIES

1. The Assistant Secretary of Defense (Health Affairs) (ASD(HA)) shall review annually compliance with this Directive.

2. The Secretaries of the Military Departments, or their designees, shall ensure compliance with this Directive.

3. The Surgeon General of each Military Department shall:

a. Ensure compliance with this Directive within the MTFs and DTFs of his or her respective Military Department.

b. Conduct an annual evaluation of the effectiveness of this Directive in reducing the overall complication and mortality rates for treatments and procedures within his or her respective Military Department and shall fulfill the information requirements in subsection G.2., below.

G. INFORMATION REQUIREMENTS

1. At the end of each calendar year, each MTF and DTF commander shall provide a report to the Military Department Surgeon General through the medical chain of command. The report shall contain a 12-month summary of complication and mortality rates for DoD health care providers within the MTF or DTF and actions taken regarding DoD health care providers whose complication or mortality rates, or both, were outside the prescribed norms.

2. Results of the evaluation conducted under paragraph F.3.b., above, along with an overall summary of complication and mortality rates and actions taken regarding DoD health care providers with rates above the norm, and a copy of the prescribed norms in use during the reporting period shall be forwarded to the ASD(HA) through the Secretary of his or her respective Military Department within 45 days following the end of each calendar year.

H. EFFECTIVE DATE AND IMPLEMENTATION

This Directive is effective immediately. Forward one copy of implementing documents to the Assistant Secretary of Defense (Health Affairs) within 90 days.

CASPAR W. WEINBERGER
Secretary of Defense

November 17, 1983
NUMBER 6025.2

ASD(HA)

Department of Defense Directive

SUBJECT: DoD Nonphysician Health Care Providers

Reference: (a) Secretary of Defense Memorandum, "Improvements Needed in Non-Physician Health Care Provider Programs," August 18, 1983 (hereby canceled)

A. PURPOSE

This Directive:

1. Establishes policy, prescribes procedures, and assigns responsibilities regarding supervision, duties and responsibilities, and education and training of DoD nonphysician health care providers.

2. Cancels reference (a).

B. APPLICABILITY AND SCOPE

1. This Directive applies to the Office of the Secretary of Defense and the Military Departments.

2. Its provisions cover DoD military and civilian nonphysician health care providers in military medical treatment facilities (MTFs), as defined in section C., below.

C. DEFINITIONS

1. DoD Nonphysician Health Care Providers. Military or civilian personnel, other than doctors of medicine or osteopathy, who are authorized and responsible for determining, starting, or altering the regimen of medical treatment provided to a patient, either on a routine or occasional basis. The generic types of DoD nonphysician health care providers included within this definition are designated, for the purpose of this Directive, as follows:

Nurse Practitioner	Clinical Assistant
Nurse Midwife	Independent Duty Technician
Nurse Anesthetist	Submarine Corpsman
Physician Assistant	

2. Regimen of Medical Treatment. A systematic course or plan directed toward the nonsurgical or surgical application of the means to effect the cure or management of a diseased or injured patient.

D. POLICY

It is DoD policy that DoD nonphysician health care providers:

1. Function under the supervision of a DoD doctor of medicine or doctor of osteopathy (hereafter "DoD physician") in all patient care activities that determine, start, or alter a regimen of medical treatment.

2. Function under an individually specified listing of duties, responsibilities, and limitations.

3. Meet specific educational requirements.

E. PROCEDURES

1. Supervision and Review

a. A DoD physician shall be appointed in writing to supervise and review the patient care of each DoD nonphysician health care provider in those duties and responsibilities involving the potential to determine, start, or alter a regimen of medical care. To ensure the effectiveness of the supervision and review process, no more than three DoD nonphysician health care providers shall be supervised and reviewed by a single DoD physician. DoD nonphysician health care providers in geographically remote locations are exempt from the requirement for direct physician supervision but shall be subject to DoD physician review as stated in paragraph E.1.c., below.

b. In MTFs in which a branch or department head is a DoD nonphysician health care provider supervising other DoD nonphysician health care providers, a single supervising DoD physician may be appointed as supervisor of the branch or department head who in turn shall be delegated the responsibility for supervising the medical treatment provided by the DoD nonphysician health care providers within the branch or department. The supervising DoD physician shall perform the appropriate review of medical treatment rendered by each DoD nonphysician health care provider within the branch or department and with the frequency indicated in paragraph E.1.c., below.

c. A structured orientation shall be provided for all DoD physician supervisors of DoD nonphysician health care providers that prescribes clearly all administrative and professional supervisory and review responsibilities. This orientation shall include but not be limited to a requirement that the DoD physician supervisor shall perform and document by signature a review of the DoD nonphysician health care provider's patient care that involves the determination, start, or alteration of medical treatment. These reviews shall be conducted a minimum of once a week for all DoD nonphysician health care providers, except for DoD nonphysician health care providers at geographically remote, inaccessible locations, such as ships at sea, for whom reviews shall be every 6 months. These reviews shall include as a minimum a 20 percent random sampling of each DoD nonphysician health care provider's patient treatments during each review period. A copy of these documented reviews shall be forwarded for review and retention by the MTF Quality Assurance Committee or responsible quality assurance monitor.

2. Duties and Responsibilities

a. Formal, written statements of the duties and responsibilities of each DoD nonphysician health care provider listed in section C., above, shall be developed by the MTF commander or designee. These statements shall be reviewed by the MTF credentials committee and reviewed and approved by the MTF commander or designee. These statements shall include at least:

(1) The routine medical treatment privileges given to each DoD nonphysician health care provider.

(2) The circumstances under which the DoD nonphysician health care provider shall consult with or refer patients to a physician.

b. DoD nonphysician health care providers granted prescription-writing authority shall be provided a written listing of those drugs that they are authorized to dispense.

c. Limitations on DoD nonphysician health care provider medical treatment privileges shall be stated in writing and shall include but not be limited to the following:

(1) DoD nonphysician health care providers performing in primary care areas such as clinics and emergency rooms shall be required to refer to a DoD physician for formal, written consultation any patient that presents the same complaint twice in a single episode of care (this does not apply to patients returning for treatment of chronic illnesses previously documented in their medical records).

(2) DoD nonphysician health care providers performing in primary care areas such as clinics and emergency rooms shall be prohibited from giving over-the-telephone diagnoses or suggested treatments that are not authorized by physician-approved protocols.

(3) DoD nonphysician health care providers will not be granted admitting authority.

3. Education and Training

a. Entry-level educational requirements shall be specified in writing by each Military Department for each type of DoD nonphysician health care provider defined in section C., above, including active duty, civil service, or contract employees.

b. Military Department training programs for DoD nonphysician health care providers shall specify minimum curriculum requirements.

c. Periodic in-service education or refresher training in applicable areas of medical treatment shall be provided and documented for each DoD nonphysician health care provider.

F. RESPONSIBILITIES

1. The Assistant Secretary of Defense (Health Affairs) shall monitor the implementation of this Directive.

2. The Secretaries of the Military Departments, or their designees, shall ensure compliance with this Directive.

3. The Surgeon General of each Military Department shall ensure compliance with this Directive within the MTFs of his or her respective Military Department.

G. EFFECTIVE DATE AND IMPLEMENTATION

This Directive is effective immediately. Forward one copy of implementing documents to the Assistant Secretary of Defense (Health Affairs) within 120 days.

PAUL THAYER
Deputy Secretary of Defense

Chairman SIMPSON. Yes, I believe you have a statement, a short statement.

Mr. TUCKER. Thank you, Mr. Chairman.

I'd like to submit a prepared testimony, if you please, and read a brief statement.

I am pleased to be here on behalf of the Inspector General of the Department of Defense to tell you how our organization monitors the Department's overall efforts to ensure quality of medical care.

Mr. Chairman, the Inspector General is only one of several organizations within DOD involved in reviewing the quality of medical care. The prime responsibility, of course, belongs to DOD's medical professionals and to the quality assurance organization that Dr. Clinton describes in his prepared statement.

In addition, each of the military departments has a staff of qualified medical inspectors who perform periodic reviews of medical facilities in their respective departments.

We also have with us today Rear Adm. Thomas W. McKean, Dental Corps, U.S. Navy, who is the Inspector General of the Naval Medical Command. He will be able to answer your questions about how his inspectors go about their work and how his organization fits into the chain of command.

In addition, each military department has an audit organization that provides audit services as required for DOD's medical community.

I must emphasize, though, that these organizations do not have medical professionals on their staff, and, therefore, do not directly examine the quality of medical care during their audits.

The last link in the chain of inspections is our organization, which is headed by Mr. Joseph H. Sherick, who is the Inspector General of the Department of Defense.

As with the services audit organizations, Mr. Sherick does not have full-time medical professionals on his staff, but he does retain the option of obtaining competent medical advice should the need arise during an audit, investigation or inspection.

In my prepared testimony, I cite two examples of how our organization has assisted the Department in monitoring the quality of medical care.

In the first example, the Secretary of Defense asked Mr. Sherick to review reports by the Air Force Inspector General concerning allegations made against a former Surgeon General of the Air Force and against a leading cardiac surgeon in the Air Force.

In this review, Mr. Sherick worked with a nationally recognized physician. The aim of the review was to verify the facts in the report, and to evaluate the actions taken in response to the allegations.

In this instance, questions concerning the quality of medical care given to specific patients were dealt with by a team of military surgeons, and, ultimately by the Society of Thoracic Surgeons. Both of these organizations worked independently of Mr. Sherick's efforts.

In a second example, we examined the procedures and records used at six military hospitals for granting privileges to health-care providers, for controlling emergency room functions, and for supervising physician assistants. We also evaluated the procedures used to obtain and process data on the education, experience and compe-

tence of health-care providers. In this audit, we applied the standards for procedures and recordkeeping set by the Joint Commission on Accreditation of Hospitals.

We did not evaluate directly the quality of medical care given to specific patients. This review is being continued at 17 additional military hospitals by the services audit organizations.

Mr. Chairman, that ends my brief statement. I'm sure that Dr. Clinton, myself, or Admiral McKean will be happy to answer any of the questions you might have.

Chairman SIMPSON. Thank you very much, Mr. Tucker. That's very helpful. Both of you.

[The prepared statement of Alvin Tucker, Deputy Assistant Inspector General for Auditing, Office of Inspector General, Department of Defense, Washington, DC, follows:]

PREPARED STATEMENT OF ALVIN TUCKER, DEPUTY ASSISTANT INSPECTOR GENERAL FOR AUDITING, OFFICE OF THE INSPECTOR GENERAL, DEPARTMENT OF DEFENSE, WASHINGTON, DC

Mr. Chairman and members of the Committee, I am pleased to be here today on behalf of the Inspector General of the Department of Defense to tell you about our efforts to insure that DoD policies and mechanisms for quality medical care are carried out.

I will begin with a brief explanation of the structure of the Inspector General's organization within DoD and then explain how that organization fits into the Departments' overall efforts to insure quality medical care for our people.

Organization and Responsibilities

The Office of the Inspector General for the Department of Defense was established by Congress in September 1982. In March 1983, Mr. Joseph H. Sherick, who at that time was the Assistant to the Secretary of Defense for Review and Oversight, was nominated by President Reagan to be the first Defense Department Inspector General. His nomination was confirmed by the Senate in April 1983.

The Defense Inspector General's organization has three operational elements. They are:

o The Assistant Inspector General for Auditing, who performs audits throughout the Department of Defense, as well as within the Office of the Secretary of Defense, the Joint Chiefs

of Staff, the Unified and Specified Commands and the Defense Agencies.

o The Assistant Inspector General for Investigations, who is the investigative arm of the Defense Inspector General's office. His primary mission is to investigate major cases of theft, fraud and corruption anywhere in the Department, with special emphasis on the procurement process. He also operates the Defense Hotline.

o The Assistant Inspector General for Inspections who performs inspections and handles special inquiries that do not warrant an audit or criminal investigation. His office is solely responsible for providing the inspection coverage of the Defense Logistics Agency and other Defense Agencies.

Other major elements of the Inspector General's office issue policy applicable to all internal audit, contract audit and investigative organizations within the Defense Department and maintain oversight of the activities of these organizations. They also resolve disputed audit findings and recommendations and follow up on audit findings and recommendations to ensure that agreed upon corrective actions are taken.

The Defense Inspector General is only one of several organizations involved in reviewing the quality of medical care. The primary responsibility, of course, belongs to the

staff and managers of DoD's hospitals. These hospitals, in turn, are supported and monitored by Quality Assurance organizations within each of the Military Departments and by Dr. Clinton's Directorate in the Office of the Secretary of Defense.

In addition, each of the Military Departments has a qualified staff of medical inspectors who can evaluate the quality assurance systems at military hospitals and treatment centers. In the Army and the Navy these inspectors are part of the Surgeon's General's organization in their respective Departments. These organizations also report to their Departmental Inspector General. In the Air Force, the Inspector General maintains his own Medical Inspection Directorate to conduct his inspections worldwide.

The Service inspectors general perform comprehensive management inspections of medical units, activities or facilities, as well as conduct investigations involving specific allegations of less than quality medical care being delivered by a facility. The composition of the inspection teams include medical, dental, nurse and medical service corps personnel who have a background plus practical experience in the areas they review. The management inspections are conducted at each facility every 2 to 3 years and quality assurance systems are an item of special interest during the inspection. During an investigation, inspectors generally take statements from witnesses and gather documentary and physical evidence to prove

or disprove the allegations that have been made. Potential criminal matters discovered by inspectors general during either their management inspections or investigations are referred to the appropriate criminal investigative agency for further investigation.

Each of the Military Departments also has an internal audit organization that does reviews of medical facilities. These organizations are the Army Audit Agency, the Air Force Audit Agency, and the Naval Audit Service. However, these organizations do not have qualified medical professionals on their staffs, so their reviews of quality assurance programs are limited to determining whether approved policies and procedures have been implemented.

The final link in the inspection chain is the Defense Inspector General. The Inspector General has a broad mandate to cover a wide range of matters related to health care. For instance, we audit the Civilian Health and Medical Program of the Uniformed Services, popularly known as CHAMPUS. We have also reviewed the operations of the Uniformed Services University of the Health Sciences. In addition, we have reported on the readiness of medical units, on internal controls in hospitals, and on how well the Services use Medical Service Corps officers. However, the Inspector General does not retain qualified medical professionals on his staff. But if he sees a need to look into an allegation, hotline complaint, or other

questionable actions he has the ability to acquire competent medical expertise to assist him in an audit, investigation, or inspection.

Such a need arose in January 1982, when the CBS news program "60 Minutes" broadcast a feature story concerning the then Surgeon General of the Air Force who was a former Commanding Officer of Wilford Hall Medical Center in San Antonio, Texas. The broadcast alleged that a leading cardiovascular surgeon on the Wilford Hall staff, and others, provided negligent medical care to a patient during surgery. The broadcast also said the Surgeon General of the Air Force knew about the problem but did not take effective action to correct it. This broadcast came to the attention of the Secretary of Defense who immediately ordered an investigation by the Air Force.

In June 1982, after a six-month investigation, the Inspector General of the Air Force reported that:

o Although the prior commander of Wilford Hall was not involved in any criminal wrong doing, in some instances he could have exercised alternate and preferable management actions. However, the choice of procedures used in the circumstances did not equate to general mismanagement in the 1977-78 period.

o The normal administrative and management procedures for advanced training were not followed in approving the surgeon's six-month fellowship with the private surgical association in Milwaukee.

o There were no legal or professional requirements for notification of the Milwaukee surgical association of the concerns raised about the surgeon's competence.

o Established credentials procedures were not followed.

o The Air Force medical service practice of allowing Air Force physicians to spend the majority or all their careers at Wilford Hall could have been a contributing factor to the surgeon's problem.

After release of the Air Force Inspector General's report, the staff of the Office of the Secretary of Defense recommended that the Secretary initiate his own investigation of the matter. The Secretary of Defense directed such an investigation, and asked Doctor Theodore Cooper, a cardiologist with extensive government, academic and private sector experience, and Mr. Joseph Sherick, the then Assistant to the Secretary of Defense for Review and Oversight, to evaluate the actions taken in response to the allegations made about the cardiac surgeon and to review the Air Force Inspector General report. The

Cooper/Sherick report, which was completed in December 1982, concluded that there were sufficient reasons to be concerned about the doctor's performance as a cardiac surgeon during the period 1975 through April 1977.

Follow-on Audit Coverage of Medical Quality Assurance

After reading the Cooper/Sherick report, the Secretary of Defense directed the Secretaries of the Army, Navy and Air Force to immediately put into place proper safeguards to insure that a situation similar to the events at Wilford Hall could not happen again. He asked the Assistant Secretary of Defense (Health Affairs) to monitor their efforts and provide periodic asessments. Finally, he requested Mr. Sherick who was then the Inspector General of the Department of Defense to give military health care a high priority in the scheduling of audits and to independently validate through the audits the effectiveness of the steps taken by the Military Departments to insure quality care at our medical treatment facilities.

Mr. Sherick has undertaken to fullfill the Secretary's request by initiating two audits to evaluate medical quality assurance practices in the Department of Defense. The first of the audits was a quick review by the Office of the Inspector General of the credentialing of health care providers, supervision and use of physician assistants and emergency room functions at six military hospitals (two in each Service). These

areas were selected for review because of their direct relationship to the quality of care and because standards for these areas had been set by the Joint Commission on Accreditation of Hospitals. I want to emphasize that this audit did not look directly at the quality of medical care itself. Rather it focused on whether the standards set by the medical profession in these areas were being adhered to. On February 10, 1984, we issued our final report on this review.

The review showed that at the six hospitals visited, procedures for granting privileges to providers, emergency room functions, and supervision of physician assistants needed to be strengthened or revised to conform with guidance set by the Joint Commission on Accreditation of Hospitals. Specifically, in the granting of privileges to health care providers, the hospitals were not uniformly obtaining, validating and keeping data on the capabilities and performance of providers. Procedures did not uniformly describe how and what type of medical privileges should be granted. Further, three hospitals did not require providers to renew and make changes to their privileges before expiration or require supervisors to formally appraise the medical performance of providers before renewing their privileges. Data in credentials files of providers did not contain information on the performance of providers and their qualifications so that credentials committees would have sufficient data upon which to base the granting or renewal of privileges.

Also, at all six hospitals the scheduling of credentials committee meetings at inconsistent intervals contributed to the expiration of privileges granted to health care providers and to heavy workloads on the committees. At two hospitals where the quality of care rendered by two physicians had been questioned by staff members, the hospital commanders and/or credentials commitees did not take firm action to suspend or withdraw privileges. At one hospital, the privileges of a physician were reinstated the day before the physician resigned and before there was evidence warranting reinstatement. Also, the anonymity of a witness against a member of the medical staff was not maintained until notification of a formal hearing or completion of an investigation.

In regard to emergency room functions, representative samples of emergency room records were not being selected for peer review at five hospitals to evaluate the appropriateness of care rendered. At four hospitals, emergency room treatment records also were not continuously reviewed for completeness and legibility.

The review showed that physician assistants were not referring patients to physicians when patients returned with the same medical complaints. Also, the ratio of supervisory physicians to physician assistants varied among the hospitals visited. Further, supervisory physicians were not uniformly reviewing the medical records of patients seen by physician assistants.

It should be noted that the scope of this review was very narrow because it was intended to provide a quick assessment of conditions in the areas reviewed. Accordingly, the results cannot be used to describe the prevalence of these conditions throughout the 167 Department of Defense medical centers and hospitals. Also, the deficiencies that we observed in the process cannot be equated with the actual quality of care delivered. However, as mentioned previously, the processes and procedures we reviewed are used as markers of the quality of care by accrediting agencies.

The second and more comprehensive audit that we began is a DoD-wide audit of medical quality assurance and incident reporting. It is a joint audit effort by the Auditors General of the Army, Navy and Air Force and the Office of the Inspector General, Department of Defense. It addresses six areas of medical treatment facilities operations and management in each Service--credentialing of health care providers, emergency care services, medical records, boards and committees, utilization reviews and incident reporting. Its scope includes an additional 17 military hospitals (6 Army, 6 Navy and 5 Air Force), including several of the large medical centers. We anticipate that the Service audit agencies will issue their draft reports on this audit in late June to mid-July for comment. We intend to issue a summary report that will highlight the results of the work by the Service auditors and our review of the selected health care procedures.

Mr. Chairman, I hope my testimony has put the role of the Inspector General into proper perspective. I am ready to answer any questions you may have.

Chairman SIMPSON. Doctor, it has been said that only physicians have the capability of monitoring other physicians.

The DOD's current organizational structure for quality assurance, uses nonphysician auditors within the office of the IG to monitor quality assurance.

In your opinion, what are the major advantages of that program?

Dr. CLINTON. Mr. Chairman, I think that the review of quality assurance can be done by many folks, and does not require in its entirety physicians or any category of health providers.

In many instances, we're talking about process. We're talking about whether procedures are established to make sure that the providers have had appropriate training, and, in fact, whether the record demonstrates that training. We're asking whether supervision was provided on a regular basis, and obviously many folks can evaluate whether those procedures and processes have been undertaken.

The quality of care issues that we're talking about for the most part deal with the structure of the medical care organizations. They do not address in a specific sense, by way of procedures, how a physician lays on hands on a patient.

Now, in that case, I think we want to turn to physicians and other health-care providers to talk about issues that surround that particular event, but that's not what the quality of care issues are today.

We're talking about credentialing, licensing, supervision, reporting of incidents, standards of mortality, standards of complication.

And, my colleagues in the Inspector General's Office can review most of those as well as I can.

So, I think we see in our system a range of activities that they can do, and we, indeed, rely heavily upon them for policy enforcement and policy review as well as at the hospital level where both physicians and nurses and other nonphysicians, indeed, administrative personnel, can follow where the procedures are being done with regularity as specified by the service regulations and our policies.

Chairman SIMPSON. Does the use of a physician consultant improve your overall quality assurance program?

Dr. CLINTON. No question about that, and in most of the audits that my colleagues in the Inspector General's Office undertake, we are in close consultation about the contents of that, what they are going to look for, what the issues are.

They turn to us about whether an issue is a clinical norm or outside the normal range of behavior, and, indeed, at the hospital level there is an interchange there also.

So, yes, they have access to us, they have access to consultants that they bring in, in a broader sense. I am only saying that a number of those things, I think, can be done without excessive consultation, that's useful and necessary.

Chairman SIMPSON. Do you think your quality assurance procedures are those that direct themselves mostly to prevention of problems of quality of care, or are they set up to deal with quality assurance problems after they have occurred?

Dr. CLINTON. Mr. Chairman, there is some of both. Let me just give an example.

On the issue of supervision of nonphysicians, clearly, that is a preventive, to use that word, exercise. We're trying to be sure that nonphysicians who always intended to be under the supervision of someone are, indeed, supervised on a regular and well-defined basis. That, I think, is prevention.

We have other policy procedures, for example, requiring that commanders and supervisors respond very rapidly and quickly to allegations of misconduct, alleged malpractice, unethical behavior, and further policies that require the system to report to our civilian colleagues an instance in which a provider has been released from our services, either with no clinical privileges or restrained clinical privileges.

Now, those are specific mechanisms to deal with an event that may occur today or tomorrow. The others, as I noted, I think, are of the preventive nature.

Chairman SIMPSON. Do you have specific policies or are you in the process of establishing specific policies to address the trends in quality of care problems that occur in a certain facility, or under certain medical procedure, or in certain DOD hospitals, or by an individual physician?

Are you able to tack it down to those things?

Dr. CLINTON. Yes, Mr. Chairman, we are.

In the directive already in place, that deals with standards of performance for providers, we have established mortality norms, death rate norms. Those norms have been calculated on the basis of our own experience. We are not comparing military physicians and the civilians who work with them with a medical care system separate from them, say, the civilian sector of the United States in general.

We now have that data, and it will come in to us on an annual basis. It is provided to us by the facility, by specific mortality event in which we have established that 1 percent or whatever that norm might be for that procedure, and by provider.

The names of providers, I would point out, are not provided to us. I don't need to know that. But, the system needs to know that at the local level.

So, I'll have a report that says provider 101 had a mortality experience with regard to, let's say, coronary artery repair, of *x* percent, and that is so many points higher than the norm.

The system requires that that be reduced, whether, indeed, that surgeon perhaps is taking the most serious patients in the hospital. Indeed, the most serious patients in the whole region.

Anyone would expect it. So, there's a review of each of those instances. I should point out that there has been a mortality review in all of our hospitals for some time. This was not started just with the quality assurance program, but all surgical deaths are reviewed.

But, now, we have a regularized system and the data comes to us for our review on a regular basis. I have discussed mortality rates. We are now moving to establish complication rates.

For example, if a patient returns to the operating room within an *x* period of time for the same event, because bleeding occurred or an infection developed, when those are beyond the norms that we have established from our own military experience, then they,

too, would be reported in the system and dealt with by counseling and review at the treatment facility level.

Chairman SIMPSON. In your personal opinion or any one there at the table, Doctor, what are the greatest difficulties or the greatest disincentives to establishing effective quality assurance programs?

Dr. CLINTON. My own experience in discussing this with doctors, predominantly doctors, in the limited time I've had to discuss the issues with them, I think as much as anything it's a concern that some things happen to make the public impose a review of their performance.

Doctors like all other people would like to think that they are doing a good job, and in the past, I think we all thought they were. But, I think that nearly every physician I talk with recognizes that the system is so large, there are so many people involved, the science and art of medicine is now so complex, that, indeed, there is a spoiled apple in the barrel from time to time, and we need to set up procedures to monitor against that.

Indeed, there are other physicians who believe in their own minds that they really are practicing absolutely first rate medicine. And, in the past, there could only be sort of an allegation, "Dr. Joe, we really don't think you're handling that kind of patient correctly."

Now we have a mechanism that quantifies that, and I've seen it and talked with physicians who said:

> You know, when you presented that complication rate experience to me, you're right. I thought I was doing that well, but I see that my colleagues have a better result than I do. I'll take care of it. I'd like to have this kind of training for 2 weeks or a refresher course in this or I simply see my error in judgment and I've corrected that.

And, these actions can be monitored.

I find few physicians really resist it when you can talk to them about what we're trying to do, and that is, to provide care for the patient's benefit.

I think it can be explained. I think the resistance is one more bureaucratic, so to speak, process being placed on them. Indeed, it requires more paper work; they've got to fill out a bit more forms, and someone else in the hospital has to be taken away from patient care to take care of this quality assurance program.

So, there is a bite from that standpoint. I think they fear one further extension of the paper work and the bureaucracy that surrounds American medicine. But, I don't find too many people, if you sit down and talk with them for 30 minutes, that can make a case that it shouldn't be done.

Chairman SIMPSON. Did you have something to offer, Admiral?

Admiral MCKEAN. Yes, sir, Mr. Chairman.

I would like to say along the same lines, that that is the one thing that we've found with the quality assurance program when inspecting our various hospitals. There probably really wasn't in the past. You must have complete involvement of the medical staff. Without that, it doesn't work. It's a paperwork exercise. We have found during the last 12 to 18 months, I speak for the Navy, that we have gotten much more involvement by going in and teaching program involvement.

I have a medical officer on my staff that's in quality assurance. Once we have gotten the participation and explained to the medical staff, we think it's gone forward and has become really a great thing during this last 12 months. It helped us in our health-care delivery system.

Chairman SIMPSON. I think that's very true, what you say. It's very helpful.

Maybe you doctors and lawyers, like university professors, who have learned the fine line between divinity and tenure sometimes, and I think that's a propensity in my former profession and in yours, and if you can point out gently to them, you know, that what this is without bruising those massive egos, the lawyer and the doctor, I think that you can get a good result.

I think it sounds to me as if you do that. Would you say that you do that?

Dr. CLINTON. I think we do that, and I think we can demonstrate its worth both now and in the future.

The other point I would add is that I think it does take a philosophy of not being accusatory from the very beginning. I'm not interested in finding out who did something wrong; I'm interested in finding out why an event occurred.

I think as soon as we make it clear, like in a negotiation process, we're trying to find source of the issues, why the incident occurred, rather than immediately placing blame.

Because many of the things, the majority of the things, that come to us can simply be corrected. That's not impossible.

Chairman SIMPSON. Well, you've given some very thoughtful responses, gentlemen, and you certainly have made great strides there and it's impressive, from this brief, very brief review.

I thank you very much. Very helpful.

[The responses of the Department of Defense (J. Jarrett Clinton, M.D., and Alvin Garrett) to written questions submitted by Hon. Alan K. Simpson, chairman of the Senate Committee on Veterans' Affairs, follow:]

RESPONSE OF THE DEPARTMENT OF DEFENSE (J. JARRETT CLINTON, M.D.) TO WRITTEN QUESTIONS SUBMITTED BY HON. ALAN K. SIMPSON, CHAIRMAN OF THE SENATE COMMITTEE ON VETERANS' AFFAIRS

Question 1. What specific policies, procedures, and follow-up mechanisms have you established which ensure that peer review committees in individual DoD hospitals perform quality assurance reviews?

Answer 1. The Department of Defense does not have an explicit policy governing quality assurance reviews. The medical facility commander is reponsible for establishing, maintaining, and supporting the hospital's quality assurance program. The Services utilize Joint Commission on Accreditation of Hospitals standards which define the procedural mechanisms for documenting quality asssurance activities. Each Service's inspector general periodically visits each medical treatment facility to evaluate compliance with the published guidance on quality assurance. Both the DoD Inspector General and the Health Affairs Office of Professional Affairs and Quality Assurance are available to follow up on the Service specific quality assurance efforts.

Question 2. How often are such reviews conducted?

Answer 2. The frequency of facility-level peer reviews is specified by the standards published by the Joint Commission on Accreditation of Hospitals. The standards state that the monitoring and evaluation of the quality and appropriateness of patient care and the clinical performance of all individuals with clinical privileges is accomplished by documented monthly meetings of the clinical departments or, in a small facility with a nondepartmentalized staff, by a monthly meeting of the medical staff.

Question 3. To whom are the results of the reviews transmitted?

Answer 3. The results of the reviews are for internal use at the facility performing these reviews. However, the number and substance of these reviews are closely scrutinized during periodic Joint Commission on Accreditation of Hospital accreditation surveys and military department inspector general onsite evaluation visits. The JCAH survey reports and the Service medical inspector general reports are sent to the hospital's higher headquarters for review.

Question 4. The Department of Defense Inspector General relies on the medical expertise of an outside physician consultant in certain quality assurance audits. In what ways does the role of this physician consultant aid or improve DoD's overall quality assurance activities? Does the expertise provided by the outside physician consultant supplement, verify and/or lend credibility to the consultant provided to the Inspector General by DoD physicians?

Answer 4. The Secretary of Defense retains Theodore Cooper, M.D., Ph.D. as a special consultant on medical issues. Dr. Cooper has worked closely with the DoD Inspector General and the Assistant Secretary of Defense (Health Affairs) in identifying and prioritizing areas within the military health care system that should be audited for quality assurance effectiveness. DoD's experience has been that the presence of an outside consultant, especially of the caliber of Dr. Cooper, can be beneficial. Specifically, it has served to focus attention on particular areas of the DoD quality assurance effort that were in need of evaluation. It has also served to defuse potential DoD critics who might claim bias in quality assurance evaluation and review if the process were conducted completely with Department of Defense personnel.

RESPONSE OF THE DEPARTMENT OF DEFENSE (ALVIN TUCKER) TO WRITTEN QUESTIONS SUBMITTED BY HON. ALAN K. SIMPSON, CHAIRMAN OF THE SENATE COMMITTEE ON VETERANS' AFFAIRS

Question 1. What resources are allocated to the Office of Inspector General, including full-time auditors and travel funds, during the course of a fiscal year to support quality assurance audits?

Answer 1. The Inspector General, DoD has a staff of about 10 auditors who perform audits of the Civilian Health and Medical Program for the Uniformed Services (CHAMPUS), the Uniformed Services University of Health Sciences and the direct health care systems in the Military Services. Additional auditors may be assigned to this staff if a particular audit requirement exists. Our audits of the health care systems encompass the operations of the hospitals and clinics, professional personnel staffing requirements, related training requirements, facilities and medical equipment.

Travel funds are allocated based on the planned audit requirements, estimated number of mandays to complete the requirements, and number of anticipated temporary duty assignments. In FY 1983 and FY 1984, we allocated over $137,000 and $102,000 in travel funds, respectively, to medically related audits. Additional funds may be reprogramed if warranted.

Question 2. What specific procedures or guidelines do you rely on to aid you in determining when a certain quality of care incident or problem requires auditing or investigating and when such a problem is only something which occurs during the normal chain of daily events.

Answer 2. Incidents involving a specific individual or circumstance are forwarded for investigation to the appropriate Military Service Inspector General, who has medical professionals on his staff. If we or the Secretary of Defense question the results of the Service Inspector General's investigation, then we take appropriate followup action, which may require our own investigation.

Systemic problems, such as lack of supervision of physician assistants or the lack of controls over emergency room functions, which may be prevalent throughout the health care system, are evaluated for audit by the Office of the Assistant Inspector General for Auditing and/or the Military Service audit organizations.

Allegations of fraud or abuse in the health care system are forwarded to the Assistant Inspector General for Criminal Investigations, Policy and Oversight, the Assistant Inspector General for Investigations, or the Assistant Inspector General for Inspections.

To determine whether a problem is an abnormal occurrence in the normal chain of daily events or a systemic weakness, we consider several factors. These include the significance of the condition, the

prevalence of the condition, whether policy guidance addresses this particular condition, the cause for the condition (i.e., noncompliance with the guidance or a lack of guidance), and finally what corrective actions should be recommended to remedy the situation. If policy changes are required to correct a problem that exists throughout the health care delivery system, then we are addressing a systemic deficiency. If the problem is in implementation by one facility or noncompliance by the facility and similar problems do not exist at other facilities, we are probably addressing an abnormal occurrence. We look for trends to accompany a systemic weakness.

Question 3. Please describe the process which is used to resolve quality assurance issues when the Assistant Secretary for Health Affairs does not concur with the findings of the Inspector General and if there is a similar process which takes place when the services' Surgeon Generals do not concur with the findings of the services' Inspector Generals.

Answer 3. Department of Defense Directive 7650.3, "Follow-up on General Accounting Office, Internal Audit, and Internal Review Reports", June 23, 1983 requires that disagreements between DoD components and DoD audit organizations be resolved within 6 months from the date of the final report.

Disputed findings and recommendations disclosed in reports by the Office of the Assistant Inspector General for Auditing are referred to the Office of the Assistant Inspector General for Audit Followup within 30 days after receipt of final management comments. The Assistant Inspector General for Audit Followup will attempt to achieve resolution at the lowest possible level within the Military Department or other Department of Defense component. If agreement cannot be reached after mediation by the Office of the Inspector General for Audit Followup, the Inspector General will attempt resolution with the appropriate Secretary of the Military Department or Director of the Defense Agency. If this is unsuccessful, the Inspector General will refer the issue to the Deputy Secretary of Defense for adjudication.

Disputed findings and recommendations disclosed in the reports by the Military Service audit organizations are forwarded through higher management levels for review and reevaluation. If resolution is unsuccessful, then the issue will be referred to the designated official for resolution within the respective Service.

Disputed findings and recommendations resulting from investigations and inspections by the Services' Inspectors General are usually resolved at the lowest possible level. However, if agreement cannot be reached, the issue may then be forwarded through command channels to the Services' Surgeons General. If resolution of the issue by the Services' Inspectors General and Surgeons General is unsuccessful, then the issue may be referred to higher management levels within the respective Service.

Chairman SIMPSON. Our final witness is Dr. John F. Beary, associate dean for undergraduate medical education and strategic planning at Georgetown University School of Medicine in Washington, DC, and the former Principal Deputy Assistant Secretary of Defense for Health Affairs, Department of Defense, Washington. All of that.

Nice to have you here.

TESTIMONY OF JOHN F. BEARY III, M.D., ASSOCIATE DEAN FOR UNDERGRADUATE MEDICAL EDUCATION AND STRATEGIC PLANNING, GEORGETOWN UNIVERSITY SCHOOL OF MEDICINE, WASHINGTON, DC

Dr. BEARY. Thank you, Senator Simpson.

I wish to re-emphasize some of the points the previous speakers have made, and which have been brought out in questions. Quality assurance is, indeed, a process, and I'd underline that word "process," whereby data on outcomes of medical diagnosis and treatment are analyzed, problems are identified, and solutions proposed.

In other words, it has a prospective orientation, not the retrospective orientation which tries to deal with problems long after they have occurred. And the overall goal is clear; to improve both effectiveness and efficiency of care.

It's worth noting in this day of consciousness about cost containment, that cost containment and quality assurance are inextricably linked. The most obvious example of this would be unnecessary surgery. If a patient undergoes, for example, an unnecessary hysterectomy, she may, of course, suffer unnecessary surgical complications or possibly even death, but she and her health plan will also incur unnecessary expense.

Although I'm going to focus today primarily on the role of the physician in quality assurance, since I am a practicing physician myself, one should bear in mind that quality problems often arise from other factors: Facilities, equipment, nonphysician health staff, and administration.

There are some bibliographies at the end of my statement to assist those of you who want to do further reading in this area.

A key concept in this discussion is that the profession of medicine depends upon trust. Medicine is a highly technical, complex activity, and lay people are dependent upon physicians doing effective self-policing.

The ethical traditions of physician behavior were reinforced in the minds of our newly graduated physicians at Georgetown last month as they took their Hippocratic oath.

This oath and the central tenet which underlies medical quality assurance is summarized by the Greek maxim, asthenes protos: "Put the interest of the patient first." That's the golden rule of quality assurance and why I'm interested, the other witnesses are interested, and all of you are interested in these very special patients, our veterans.

I'd further emphasize that U.S. medicine is really very good. But, I think we need to sustain that, improve it where it's possible, and a good quality assurance system serves to do that.

Peer review or medical self-policing is best done at the local level. There seems to be consensus on this by the other speakers.

An effective process, however, is dependent upon good administration, an effective data-gathering system—you can underline "data" gathering about four or five times—a system for prospectively establishing norms—underline "prospectively" four or five times. Norms enable one to debate about what the mortality rate should be for mitral valve replacement in the heart before the operation, not afterward when people perhaps will have an agenda of their own to defend and there may be as much emotion as exchange of data in those highly charged situations.

Norms, just to review that concept, are statistical measures of usual observed performance. They are the figures I give my own patients when they require surgery. Those who require surgery want to know, what is the mortality rate of the surgeon you are sending me to?

Those of us who are interested in strategic planning, who read Megatrends or any other number of things, know about the change in the current environment and know that we're in a new age.

Consumers take more of an interest in their health care, they are more sophisticated, have better information, call for accountability, and there is more competition.

And, finally, the confidentiality of peer review data must be assured. If it is not, you really will not get information; there will be some creative accounting going on, and what you get will have little to do with reality. So, confidentiality must be maintained, and then it can work.

In my opinion, the factors which inhibit candid peer review from personal experience and from administrative experience, are fivefold.

First are the social pressures which result from personal friendships with one's fellow physician coworkers. Now, this has a plus side, too. The fact that you have cohesion with people you work with makes you work together better as a team. So, that's a positive side, but the other side of the coin is that it's hard to blow the whistle on a friend.

And, for instance, page 26 of the December 1982 Cooper Report speaks to that inability to be self-critical.

Another one is fear of a lawsuit. I was presented a case at lunch the other day, not involving a hospital in this city, of a heart surgeon who only did 10 cases a year. You might understand, he had a very high and unacceptable mortality rate. The cardiologist in this conference raised the question as to whether he should be operating at all, and the cardiologist shortly thereafter received a call from the gentleman's attorney saying that his client's reputation had been damaged and they were going to pursue this in court.

So, it's a very real concern. Retaliation and abuse directed at the whistle blower—physician whistle blower. Fourth, embarassment to a hospital or institution. And, fifth, inadequate data systems for gathering basic quality assurance data.

In terms of a problem list, you might want to consider—and these are just general comments that could be directed at any large system since I have a high opinion of the VA; they should be just looked at as constructive areas in which one might want to assess

how well you're doing—analysis of the local hospital level peer review and quality assurance mechanism.

This is the foundation. If this is not right, the stuff above has little hope of working. Garbage in, garbage out or the "GIGO" problem.

This also requires, and I'd emphasize this, that you have to have a good local level information system. What gets measured, gets done.

The next major area is that you have to have meaningful performance norms. I think you're making an erroneous assumption if you assume this is being done already.

I think most people do assume this, which is why in today's more competitive environment, you don't see competing HMO's and other organizations who are advertising their services, saying that we give "high quality medical care." Everybody expects it. You're not going to buy from someone who doesn't. When you buy a car, you don't see an ad that says this car runs. You assume it runs.

So, I would just emphasize that there is a need to have these norms, and to have them prospectively determined, and here in my written testimony, I cite a case where there was controversy about a heart surgeon with a coronary bypass graft patency rate—one of the most common operations done in the country—of about 46 percent.

Most centers that do heart surgery will run about 90 percent, and none of this surgeon's peers had lower than 70 percent. However, in the absence of accepted established norms at this institution, a huge debate ensued and it's, in effect, still going on to this day in some quarters.

But, it does reemphasize why we need these norms.

I was delighted that Dr. Clinton said that DOD directive 6025.1, which requires mortality rate norms to be set, and was signed by Secretary Weinberger over a year ago, in April 1983, is starting to make some progress. In a sense the slow pace is a self-criticism because I was in charge of trying to implement that for 6 months, and nothing much was happening.

There was tremendous resistance to the idea, which is not surprising. There is a lot of emotion tied up in this subject. Change comes hard. I do not want to be overly dramatic, but if you just think what happened when Vesalius challenged what Galen had been teaching about anatomy for 1,000 years, it took decades to finally get acceptance for a new and correct way of doing things.

So, it's not so much the concept, but it's the emotion tied up in the old way of doing things. I have close contacts with two of the three services here in town at the working level; people who are operating on and caring for patients, and they are unaware that these mortality rates are being used at the present time.

But, I'm happy to see they are, and I look forward to their comments and discussions now that they are in place and effectively being used. They do serve well the self-interest of the patient, which is obvious, and the doctor as well.

Sharing information, on decredentialed doctors, an information system to analyze malpractice claims—if you're paying out a large number of dollars per year, you want to know why you're doing it—and the need to protect medical whistle blowers—the DOD IG

report of February 10 speaks to that—are covered in my written statement.

And, a final thing that affects all health systems here would be detection and rehabilitation of drug and alcohol impaired physicians. By definition, when you're impaired, you don't have the judgment to recognize you've got a problem. And, in a big system like the VA's you probably have at least 100 doctors who are going to work at some point during this week with some degree of drug or alcohol impairment.

As you know, 10 percent of all occupations have significant drug or alcohol impairment.

I want to reemphasize the need for a prospective system. If you have an early warning system and know expected mortality rates, you can act. If it's supposed to be under 5 percent, you can react when it's 7 or 8 percent early on, rather than late when it's 20 or 25 percent.

So, that's the reason to have these things.

Chairman SIMPSON. If you could just accelerate your remarks.

Dr. BEARY. Surely, Senator.

The final thing I'd speak to is the role of Inspector General level oversight. It seems to have worked well in DOD, as you have heard.

In summary, I would say you would need to, from my prospective, get a problem list of your top three concerns, I mentioned what some of them are from my perspective, and get a strategy to solve them. In conclusion, an optimally functioning VA quality assurance system will benefit everyone, the taxpayer who funds it, the legislator who provides oversight, and the doctor who preserves the reputation and trust placed in the profession, and, most importantly, the patient who will receive the most effective medical care possible.

Chairman SIMPSON. Thank you very much.

[The prepared statement of John F. Beary III, M.D., associate dean for Undergraduate Medical Education and Strategic Planning, Georgetown University School of Medicine, follows:]

PREPARED STATEMENT OF JOHN F. BEARY, III, M.D., ASSOCIATE DEAN, GEORGETOWN UNIVERSITY SCHOOL OF MEDICINE, WASHINGTON, DC

Quality Assurance is a process whereby data on outcomes of medical diagnosis and treatment are analyzed; problems of substandard care are identified and solutions are proposed. The overall goal is to improve the effectiveness and efficiency of medical care.

It is worth emphasizing that medical cost containment and quality assurance (QA) are inextricably linked. The most obvious example of this is unnecessary surgery. If a patient undergoes an unnecessary hysterectomy, she may of course suffer unnecessary surgical complications or possibly even death, but she and her health plan also incur unnecessary expense.

The history of quality assurance is an interesting one. The Visigoth culture found in the South of France until about 500 A.D. had high medical standards and an interesting approach to QA. Doctors were required to pay a deposit to the patient's family before starting treatment. If the physician's treatment were successful, the deposit was returned to the doctor and the customary fee was paid as well. However, if the patient died, the doctor forfeited the deposit and was required to spend a period of mourning with the family of the dead patient.

Although, I will focus primarily on the role of the physician in quality assurance, one should bear in mind that quality problems often arise from other factors such as facilities, equipment, non-physician health staff, and administration. Extensive bibliographies are available in the references cited.

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The profession of medicine depends upon trust. Medicine is a highly technical, complex activity and lay people are dependent upon physicians doing effective self-policing. The ethical traditions of physician behavior were reinforced in the minds of our newly graduated physicians last month, as they took the Hippocratic Oath. This oath and the central ethical tenet underlying medical quality assurance is summarized by the Greek maxim "Asthenes protos" or the patient first. This is the Golden Rule of quality assurance.

Peer review or medical self-policing is best done at the local level. An effective peer review process is dependent upon good administration, an effective data gathering system, a system for prospectively establishing norms (statistical measures of usual observed performance), and a policy of assuring the confidentiality of peer review data.

Factors which inhibit candid peer review

There are five major factors which inhibit physician peer review:

1. Social pressures resulting from personal friendships with one's fello workers.

2. Fear of a law suit.

3. Retaliation and abuse directed at the physician whistleblower.

4. Embarrassment to a hospital or institution.

5. Inadequate systems for gathering basic quality assurance data.

Problem List

My perspective from my Department of Defense and private sector experience is that your committee will probably want to examine the following quality assurance problem areas:

1. Analysis of the local, hospital level peer review and quality assurance (QA) mechanism. This is the foundation on which everything rests. If it is not well designed and administered, there is no hope of having an effective QA system.

2. Need for meaningful performance norms.

   These morbidity and mortality norms must be prospectively determined and oversight applied to see that they are used.

   In one case with which I am familiar a heart surgeon had a coronary bypass graft patency rate of 46% at 30 days after the operation. For comparison most centers would have a patency rate of about 90% and this surgeon's peers had rates no lower than 70%. However, this

doctor in the absence of accepted, established norms at his institution said that he only operated on the oldest and sickest patients and so that of course his results would be poorer.

DoD directive 6025.1 which requires mortality rate norms to be set for the thirty most common surgical procedures was signed by Secretary Weinberger well over a year ago in April 1983. However, I am told that next to nothing has been done to implement it which serves to illustrate the extreme sensitivity and resistance to change which you will encounter if you choose to work in this area.

In summary, it is very difficult to accuse one's physician peer of incompetence. The only way that one can avoid the need for physician whistleblowers is to collect cumulative mortality data on everyone and compare it to norms.

3. Sharing Information with the public concerning health care providers who are incompetent or morally deficient. It is my understanding that the Veterans Administration does a good job in this respect, utilizing the National Clearinghouse in Texas which is run by the Federation of State Medical Boards.

However, I would caution that ongoing oversight of this delicate subject is needed because of the barriers to candid peer review which I cited earlier in my testimony.

For example in the DoD Inspector General's report of 10 February, 1984 a case was cited of a doctor who had sex with a patient and had his privileges suspended. However, his privileges were restored for 6 hours on the day before he was terminated from service thus evading the requirement to report him to the National Clearinghouse.

4. Need for an information system to analyze malpractice claims. Lessons learned can thus be fed back to the hospitals via a risk management system. The VA of course has such a program, but this is mentioned for the sake of completeness. If one finds for example that the number one cause of malpractice suits is failure to diagnose heart attack, then appropriate measures can be taken to solve this quality problem.

5. Need to protect medical whistleblowers from abuse or retaliation. (See page 25 of the DoD IG report of 10 February, 1984).

6. Detection and rehabilitation of drug and alcohol impaired physicians. Ten percent of Americans from all walks of life suffer drug and/or alcohol impairment. Because of the stress associated with the practice of medicine and the ability to self-medicate with controlled drugs, it is likely that doctors have an abuse rate at least equal to and perhaps higher than that of the general population. As in all occupations, detection and rehabilitation are major concerns. However, the implications of impaired physicians involved in patient care are of special concern.

7. The role of Inspector General level oversight. It is a well accepted management principle that program implementation and evaluation are separate functions. It is not wise to let people write their own report cards. Thus a VA Inspector General with medical quality assurance oversight responsibilities is in my view a sensible idea worthy of consideration. The effectiveness of the DoD Inspector General in medical oversight activities lends support to this concept.

In summary, because of its status as the largest health system in America and due to its "closed system" structure, the Veteran's Administration has the opportunity to provide ground breaking leadership in the medical quality asssurance area.

An optimally functioning Veterans Administration quality assurance system benefits everyone: the taxpayer who funds it, the legislator who provides policy oversight, the doctor who preserves the reputation and trust placed in the profession, and most importantly the patient who receives the most effective medical care possible.

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Chairman SIMPSON. You have described a number of barriers that attend the peer review process and you have made some recommendations.

Whose responsibility is it to develop these effective quality assurance policies which might then aid them and us in overcoming some of those barriers?

Dr. BEARY. For your particular health system, I think the VA Central Office would form the policies that would accomplish the goals which we all seem to share here.

Chairman SIMPSON. That's true, of course, but there's reticence there, and you speak of, often in your remarks, the word emotion, which is certainly true when you're dealing in these areas, especially if there is a threat to one's capabilities or professional skills, and that's what we're talking about. That's where we are, the bottom line.

And, I just see it as a very difficult thing to do that, doctor on doctor, without some more precise method, perhaps as exercised by the Department of Defense.

Dr. BEARY. In fact, I think I can address what you're getting at there.

For instance, in the new medicare DRG system, it's very important that you know what your length of stay is for each illness. And, in fact, now, at hospitals like Georgetown, I receive a printout of how many days my patient spends in a hospital and what the expected length of stay is. You see just by having the information visible, you tend to act on it and you tend to want to, if at all possible, stay with your peer group.

So, I think that blowing the whistle on a fellow physician, is not going to get any easier. Therefore, if everybody's performance is reviewed once a year—which it's supposed to be anyway, because credentials are up for renewal each year, but in the past, it's often been sort of a pro forma paperwork type of exercise—then you don't need a whistleblower. If you're in a surgical field which is more quantifiable, using a surgical mortality rate—surgery is the area where we heard the VA is getting the most malpractice claims—everybody's work can be reviewed and compared to norms.

Good doctors are not threatened by that.

Chairman SIMPSON. What's the relationship between board certification and quality of performance?

Dr. BEARY. Well, it would mean that at one time, the doctor had a great deal of training and was quite current, but after 5 years out, it would not have as much meaning unless there is recertification. It—I guess that would be the best way to say it. It's a look at you at one time in your life and how you're doing.

Chairman SIMPSON. So, if that look was valid then, then it seems to me the continuing education in the medical profession and particularly with the physicians is critically important in ensuring quality of performance, is that not correct?

Dr. BEARY. I think it is, and the profession makes an effort to continue to stay up to date. There is lot of new technology and information to master, and I think most physicians are committed to continuing medical education.

Chairman SIMPSON. What are the advantages that you might see in having a full-time physician on the Medical Inspector's staff

compared to just having access to outside physician expertise, and is either one preferable?

Dr. BEARY. Well, I think Dr. Gronvall raised some cogent concerns as to what kind of a physician would be intrigued by this as a career, and I think that the DOD model might be more successful. That is, you can have a stable of consultants that are called upon as needed. They are independent, outside the system. They didn't have an axe to grind. You didn't have to worry about the quis custodiet ipsos custodes "who watches the watchdog" type of issues.

So, I would think the part-time consultant approach might be the most beneficial because lay people will have a hard time cracking the code of medicine, and the IG is going to need someone who can look at the process and say one, was the process done right, and two, did it meet the goals that the VA and the Congress have set up for it to meet.

Chairman SIMPSON. I appreciate that. That's helpful.

I have some other questions, but I will pose those in writing, and I thank you for your attendance, and your assistance.

[The response of John F. Beary III, M.D., associate dean for undergraduate medical education and strategic planning, Georgetown University School of Medicine, Washington, DC, to written questions submitted by Hon. Alan K. Simpson, chairman of the Senate Committee on Veterans' Affairs, follows:]

RESPONSE OF JOHN F. BEARY, III, M.D., ASSOCIATE DEAN FOR UNDERGRADUATE MEDICAL EDUCATION AND STRATEGIC PLANNING, GEORGETOWN UNIVERSITY SCHOOL OF MEDICINE, WASHINGTON, DC, TO WRITTEN QUESTIONS SUBMITTED BY HON. ALAN K. SIMPSON, CHAIRMAN OF THE SENATE COMMITTEE ON VETERANS' AFFAIRS

Question 1. You have said that in your view, an Inspector General with medical quality assurance oversight responsibilities is a sensible idea and that the effectiveness of the DOD Inspector General in medical oversight activities lends support to this concept. In your opinion, what would be the advantages of having a full-time physician on the VA Inspector General's staff and how would this compare to having access to outside physician expertise? Would either one be preferable?

Answer 1. The options are:

(1) A full time physician on the IG's staff.

This would be the best option if a qualified and motivated doctor could be found for the post. There could be some recruiting difficulty since this is not a traditional career path.

It should be noted that if the physician were mediocre, the quality assurance process would actually be hindered and not helped.

The need for the physician to be independent from the line VA in regard to promotion, assignment, etc. is obvious

(2) Independent, external consultants. If the first option is not feasible, this could work well and certainly has at the Department of Defense.

Again the key qualifications are professional expertise, interest in quality assurance, and independence.

Question 2. In both the Veterans' Administration and the Department of Defense there are many different people and offices involved in quality assurance, including policy makers, auditors, investigators, local level committees and boards, and others.

In your view, what mechanisms should be set up to ensure that the activities of all of the groups are coordinated and that information concerning incidents, malpractice claims, and competency of professionals is transmitted throughout the system?

Answer 2. Once a proper "information system" has been set up, (see questions 3 and 4), one must perform ongoing evaluation to assure that the information is being used to identify problems and that something constructive (as opposed to defensive actions) is done about the problems which are identified.

Accountability is the key concept here. Each unit in the administrative chain must have its responsibilities clearly spelled out. Thus if a mishap occurs, the appropriate individual can be called on for an explanation as to what is being done to prevent a re-occurence of the incident in the future.

Question 3. In your opinion, how do auditors, investigators, and policy makers distinguish between problems and incidents that occur in the provision of health care services during the normal chain of events and events which are indicative of serious problems in the system?

Answer 3. This requires three elements:

1. Prospectively determined norms (age adjusted mortality rates, morbidity rates, etc.) which can be used to evaluate the results of a particular doctor or institution.

2. System of accountability (see question #2).

3. Independent evaluators who can be called upon as needed (see question #1).

Question 4. In addition to statistics on mortality rates, malpractice claims and medical incidents, are there other sets of information or markers of care which should be collected and analyzed to determine trends or problems in certain procedures, services, or care provided by certain individuals, and if so, what are they?

Answer 4.

A criterion is a predetermined element (e.g. a mortality rate for a particular type of surgery; adverse drug reactions, etc.) which reflects the judgement of health professionals as to what is important to measure in the quality assurance process.

A norm is a statistical expression of the usual observed performance, and is derived from recorded experience and/or a review of the medical literature. E.G., the norm for the mortality rate in coronary artery bypass surgery is 1 to 2%.

Suggested criteria to measure and follow are:

1. Surgical mortality rates for the five most common operations in each surgical subspecialty. (In most health systems, the majority of malpractice claims are related to surgical cases which are also the most expensive category to settle).

2. Surgical complication rates.

3. Morbidity rates, e.g.,
   (a) Hospital infection rates.
   (b) Rate of adverse drug reactions.

Additional measures which will identify problems that need to be followed include:

1. Analysis of the incident reporting system data.

2. Malpractice claims data
   - List the top ten claim categories for both claims filed and for claims settled in the reporting year, e.g. anoxic birth damage, failure to diagnose cancer etc. This enables one to assess past experience, yet also stay abreast of current claims experience (since it may take years for a claim to be settled from the time that it is presented).

A. In addition to the incidence data above, list the top ten categories of malpractice claims, by dollar amount, settled in the reporting year (include both in-court and out-of-court settlements).

Question 5. You have said that the analysis of the local hospital peer review and quality assurance mechanism is "the foundation on which everything rests" and if that is not well designed and administered, "there is no hope of having an effective quality assurance system." In your opinion, what specific policies pertaining to the structure and administration of a local hospital peer review process are essential to its effective operation and what specific monitoring procedures should be undertaken to oversee its operation?

Answer 5. The following elements are needed:

1. A good data system

2. Prospective criteria and norms of performance. (There is too much emotionalism involved in determining an acceptable mortality rate norm after a question of competence has been raised).

3. Confidentiality of peer review information. (If this is not guaranteed, needed information will not be available as it depends on the good will of the local doctors).

4. Protection of whistleblowers from retaliation.

5. An automatic, annual review of each physician's performance compared to expected norms, which is linked to credential renewal. If everyone's performance is reviewed, this decreases the need for whistleblowers.

6. Accountability from the hospital management team.

Chairman SIMPSON. I just had a couple more questions, then if I may, go back to Mr. Tucker. It was my own error that I did not get to do so, sir.

Mr. TUCKER. Fine.

Chairman SIMPSON. Because certainly you presented very interesting material, and I just want to ask you, and again I appreciate you being here, Dr. Beary, that was very helpful and you certainly have some provocative things to present.

And, so did you, Mr. Tucker, and I just wanted to check with you. You spoke of giving the health care high priority and the scheduling of audits and so on, and I understand your effort there.

And, do you have the proper resources to carry out those things, to fulfill the Secretary's directives that you quoted here? Do you have the proper resources?

Mr. TUCKER. Yes, sir, we do. We have a much broader mandate in the medical field than just quality of medical care. We are involved in the CHAMPUS program, an acronym whose meaning I can't recall at the moment.

Chairman SIMPSON. Good. If you can't and you're in it, I never have been able to.

Mr. TUCKER. And, things like internal controls over controlled substances. We have a staff of about 10 auditors who are involved in medical questions, but none of them are physicians, all of them are accountants.

Chairman SIMPSON. Let me ask you the number of times that the Inspector General has sought the assistance of outside medical expertise and the kinds of cases where he was asked to address and the frequency of the assistance provided to your office during the course of the year, if you have those or could furnish those?

Mr. TUCKER. I can furnish those statistics, but, in general, we have used the services of one nationally recognized physician for a period of 2 years.

[Subsequently, the Department of Defense submitted the following information:]

This physician is Dr. Theodore Cooper, Consultant to the Secretary of Defense and a cardiologist with extensive Government, academic and private sector experience. Specifically, in the last year, Dr. Cooper was consulted in 2 investigations involving allegations of medical malpractice and during 3 audits in the health-care area. These audits were the Review of Selected Health Care Procedures, the DOD-wide Audit of Medical Quality Assurance and Incident Reporting, and the Review of Medical Internal Controls. The Inspector General and members of his staff met with Dr. Cooper approximately every 2 months to discuss the status of audit, inspection and investigation activities that we believe required medical expertise. In addition to these meetings, we have at various times provided material to Dr. Cooper by mail and obtained his viewpoints by telephone.

Chairman SIMPSON. And, of course, we have heard throughout that only doctors can monitor doctors, and without specific medical expertise, auditors, and investigations are just not able to assess the quality of care, and, yet, there are many things, as stated well by Dr. Clinton, that you would agree on and that you could do, and that's probably the majority of things.

But, apparently you had one particular case which was of interest, the *Wilford Hall* case, which seemed to establish your auditor's credibility.

What procedures, briefly, enabled you to do that?

Mr. TUCKER. Well, the *Wilford Hall* case involved a series of allegations that were quite sensational. The Air Force Inspector General had already looked at the allegations and made a report. The Secretary of Defense asked the IG to review that report and try to verify the facts of the report, and evaluate the actions taken.

We had the advice of Dr. Cooper, while we were doing that, but the focus of the Cooper-Sherick report was not the quality of the medical care, but who knew what when, what was done when certain knowledge was made available, and was the action taken appropriate.

The question of the capability of the doctor and the care that he gave to his patients over a period of time was something that had to be, we think, quite properly dealt with by medical professionals; and there was a team of military surgeons appointed that looked at it independently as well as, as I said, the Society of Thoracic Surgeons who looked at it independently.

Chairman SIMPSON. So, it works, whatever you're up to,

Mr. TUCKER. It worked very well in this case. It brought to the attention of the Secretary of Defense, the need for improved quality assurance measures, and I think in a large measure, was responsible for establishing the very active and strong program within the Department that Dr. Clinton has described to get more data and to monitor quality assurance again by professional medical people.

Chairman SIMPSON. Just a final question. Your audit for medical quality assurance involving 17 hospitals has not yet been completed or released.

In your testimony, you mention that it addresses six areas of medical treatment.

Could you describe just swiftly the reasons why those specific areas were chosen to be reviewed, and if that choice reflects your view that these are the most important aspects of quality assurance operations, management, or generally in other facilities?

Mr. TUCKER. Those areas were chosen in consultation with Dr. Clinton and with the other people in the Office of the Assistant Secretary for Health Affairs.

They are areas of interest to them, but they also have the quality that they are areas where there are set standards, either standards set by the Joint Commission on Accreditation of Hospitals or standards set in DOD directives or regulations. Something that we can audit against in what we call a compliance type audit.

We look to see whether the markers of quality medical care are in existence, and use that as an indication of whether there could be quality assurance problems.

Chairman SIMPSON. Well, I thank you very much. This will be helpful material for us, and we'll try to keep in mind the differences in the kind of health care you furnish, the different patient loads DOD and the VA both deal with, too.

The Department of Defense deals with families who are younger or relatively more healthy perhaps than the VA which has a predominantly male patient population, service-connected and nonservice-connected, many of whom are over 65, and DOD has smaller hospitals. Those things all come into it. We'll try to weigh those,

but I think you have given us some very thoughtful things for the committee to consider.

Both Senator Cranston and I appreciate that very much as do the other committee members who will review this material here on the record and that which you will furnish for the record.

So, with that, thank you very much. I appreciate it very much all of you attending and assisting us. Thanks to the staff, particularly Cindy Alpert, a professional staff member who put this together, and Carol DeAngelus, Becky Hucks, Kay Eckhardt, Jody Sanders, very capable minority staff always, epitomized by Jonathan Steinberg, who is always of great assistance, and Julie Susman and to our chief counsel and staff director, Tony Principi, who did an excellent job here.

And, I believe that concludes our efforts. Thank you so much.

The hearing is concluded.

[Whereupon, at 11:45 a.m., the hearing was adjourned.]

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